# COMAR 10.24.15

## STATE HEALTH PLAN FOR FACILITIES AND SERVICES: SPECIALIZED HEALTH CARE SERVICES

# ORGAN TRANSPLANT SERVICES:

## REGULATORY ISSUES AND POLICY OPTIONS

**RELEASED FOR PUBLIC COMMENT**
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MHCC MARYLAND HEALTH CARE COMMISSION

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## *Acronyms*

| | |
|---|---|
| **ABMTR** | Autologous Blood and Marrow Transplant Registry |
| **BRFSS** | Behavioral Risk Factor Surveillance System |
| **CMS** | Centers for Medicare and Medicaid Services |
| **CON** | Certificate of Need |
| **CPC** | Charge per case target |
| **DHHS** | Department of Health and Human Services |
| **DRG** | Diagnosis related group |
| **ELAD** | Extracorporeal liver-assist device |
| **FAHCT** | Foundation for the Accreditation of Hematopoietic Cell Therapy |
| **FDA** | Food and Drug Administration |
| **HCFA** | Health Care Financing Administration |
| **HLA** | Human leukocyte antigen |
| **HSCRC** | Health Services Cost Review Commission |
| **IBMTR** | International Bone Marrow Transplant Registry |
| **IDE** | Investigational device exemption |
| **IRB** | Institutional Review Board |
| **LVAS** | Left ventricular assist system |
| **OPO** | Organ Procurement Organization |
| **OPTN** | Organ Procurement and Transplantation Network |
| **SHP** | State Health Plan |
| **TAH** | Total artificial heart |
| **TRC** | Transplant Resource Center of Maryland |
| **UNOS** | United Network for Organ Sharing |
| **VAD** | Ventricular assist device |
| **WRTC** | Washington Regional Transplant Consortium |

# I. Introduction

## *A. Background*

As required by State law, the Maryland Health Care Commission prepares, adopts, and updates the State Health Plan (SHP) for facilities and services that are required to obtain a Certificate of Need (CON) or an exemption from the CON program. The SHP includes the methodologies, standards, and criteria for Certificate of Need review, and priorities for the conversion of acute capacity to alternative uses where appropriate. The Secretary of Health and Mental Hygiene is authorized to adopt and revise as necessary a State health improvement plan, including the goals and policies for Maryland's health care system, and the identification of unmet needs and excess services for facilities and services that are not regulated by the CON program.

To comply with the statute, the Commission develops and promulgates policies and standards that relate to the CON program and address the availability, accessibility, cost, and quality of health care. The Commission reviews the SHP periodically and publishes any changes that the Commission considers necessary to reflect new developments in health care planning, delivery, technology, or utilization.

Organ transplantation in the United States has advanced rapidly over the past 40 years, from the initial experiments of the 1950s and 1960s through the medical, surgical and immunological breakthroughs of the 1980s and 1990s. Results from increasingly complex transplant operations continue to improve, and the survival rates of patients and of transplanted organs are rising.

Until the early 1980s, only a few medical centers performed transplants, and organ allocation was often handled on a local or regional basis. However, as transplant outcomes improved and as more patients became transplant candidates, the federal government recognized the need for a centralized, national organ distribution system assuring all patients an equal chance to receive donor organs. With passage of the 1984 National Organ Transplant Act, a national Organ Procurement and Transplantation Network (OPTN) was established to develop a system for the equitable allocation of donated organs. In addition, a national Scientific Registry was designed to compile and analyze data on all transplants performed and to suggest improvements to benefit transplant patients.

The State Health Plan has included standards and policies, as well as need projections, for organ transplant services since January 1999. Organ transplant services addressed in the current State Health Plan refer to solid organ transplants (kidney, pancreas, liver, heart and lung) and hematopoietic stem cells. The Plan states that CON coverage of other types of transplant programs will be determined by the Commission as needed.

## *B. Purpose of the Options Paper*

During 2001-2002, the Maryland Health Care Commission will update the State Health Plan for organ transplant services. This options paper, *Organ Transplant Services: Regulatory Issues and Policy Options,* has been prepared to assist the Commission in the process of updating this component of the State Health Plan by: (1) providing background information on organ transplant services in Maryland; (2) identifying key policy issues in planning and regulating

organ transplant services; (3) examining the impact of alternative policy assumptions; and (4) providing a framework for the Commission to obtain public comment on key policy issues prior to updating the State Health Plan.

In identifying and examining the impact of alternative policy assumptions, it is the intent of the paper to encourage discussion and debate in shaping the policy direction of the updated State Health Plan. While the paper does examine alternative approaches for key planning policies, it is important to recognize that the alternatives identified do not represent the staff recommendation or the full range of policy options that potentially will be considered in the process of updating the Plan. It is the expectation of the Commission that the public comment process involved in updating the Plan will identify additional policy options and approaches that merit consideration.

## *C. Invitation for Public Comment*

The Commission invited all interested organizations and individuals to participate in the process of updating the State Health Plan for organ transplant services. Written comments on this options paper had to be submitted not later than **October 9, 2001.**

The written comments received on the Options Paper were used by the Commission staff to prepare a draft updated State Health Plan chapter on organ transplant services. This draft plan was presented at the Commission meeting on November 15, 2001. The Commission circulated the draft Plan for public comment prior to formally promulgating the Plan through the regulatory process.

## *D. Planning for Organ Transplant Services*

Under Maryland law, the establishment of new organ transplant services requires Certificate of Need (CON) approval. To guide public policy governing the establishment of new organ transplant services, the State Health Plan contains planning policies, a need projection, and criteria and standards for reviewing CON applications. The current State Health Plan chapter governing organ transplant services, COMAR 10.24.15, was developed during 1998 and became effective January 14, 1999. Since the initial chapter was developed, it has been updated once, with the adoption of Supplement 1, effective February 7, 2000. Supplement 1 updated issues surrounding the inclusion of stem cell and bone marrow transplants in the chapter.

The process used to develop the initial State health policies governing organ transplant services involved consultation with experts in solid organ transplants and stem cell transplants. This options paper is the first step in the Commission's comprehensive review of the plan chapter. The paper provides an opportunity for interested parties to raise issues and discuss policy options for consideration in the Commission's review of the State Health Plan.

## *E. Organization of the Paper*

The Options Paper is organized in four major sections. Following this Introduction, Part II of the paper contains an overview of organ transplant services, including a description of the Maryland organ transplant programs and an analysis of trends in the utilization of organ transplant services. In Part III of the paper, a series of planning and regulatory issues are identified together with analysis of the impact of alternative policy options. Those planning and regulatory issues

include: types of transplants covered, method of need projection, quality of care issues, cost of care and access to care issues. A summary of the policy options is provided in Part IV.

# II. Organ Transplant Services: Overview

## *A. Maryland Organ Transplant Programs*

Organ transplant services to treat end-stage organ failure are a highly specialized area of health care. Solid organ transplant programs are currently operated by two of the 47 non-federal, acute care hospitals in the State of Maryland: Johns Hopkins Hospital, and University of Maryland Medical Center. In addition, Greater Baltimore Medical Center, Holy Cross and Sinai hospitals provide stem cell transplants. Maryland residents are also served by organ transplant programs located in Washington, D.C. and other adjacent states.

This paper focuses on programs in Maryland, District of Columbia and Northern Virginia. In Washington, D.C., five hospitals (Children's National Medical Center, George Washington University Medical Center, Georgetown University Medical Center, Howard University Hospital and Washington Hospital Center) provide solid organ and stem cell transplant services. Inova Fairfax Hospital in Virginia also provides some services to Maryland residents. In addition, several federal hospitals provide organ transplant services to eligible patients: Walter Reed Army Medical Center, National Institutes of Health and VA Medical Center.

For planning purposes, the Commission has established two regional service areas based on those developed by the Centers for Medicare and Medicaid Services (CMS), formerly known as the Health Care Financing Administration (HCFA), for the Organ Procurement Organizations (OPOs). The OPOs covering the two regions in the State of Maryland are the Transplant Resource Center of Maryland (TRC) and the Washington Regional Transplant Consortium (WRTC). TRC provides services to people living in Maryland, excluding Charles, Montgomery and Prince George's counties. Those counties are served by WRTC. WRTC also provides organ procurement services to Washington, D.C. and Northern Virginia.

There have been some changes over the past few years in the number of transplant centers and programs in the Maryland and Washington regions. Shady Grove Adventist Hospital in the Washington region of Maryland discontinued its only transplant program (kidney) at the end of 1998. Johns Hopkins Bayview Medical Center has consolidated its kidney transplant program with Johns Hopkins Hospital. United Network for Organ Sharing (UNOS), the OPTN contractor, also reports Johns Hopkins Hospital as approved for intestinal transplantation, and University of Maryland Medical Center as approved for pancreatic islet cell transplantation.

**Table 1: Distribution of Non-Federal Transplant Centers Approved for Organ and Stem Cell Transplant Services by Type of Program and Region: Maryland and Washington Regions, 2001**

| Region | Kidney | Pancreas | Liver | Heart | Lung | Intestine | Pancreatic Islet | Stem Cell |
|---|---|---|---|---|---|---|---|---|
| Maryland | 2 | 2 | 2 | 2 | 2 | 1 | 1 | 4 |
| Washington | 5 | 4 | 3 | 3 | 1 | 0 | 0 | 6 |
| **Total** | **7** | **6** | **5** | **5** | **3** | **1** | **1** | **10** |

Source: UNOS OPTN Data as of September 2000; except for stem cell transplant programs (Maryland Discharge Abstract Data, DC Discharge Data, Fairfax Hospital, as of July 2001.)

**Table 2: Solid Organ Transplant Centers Within Each CMS OPO - Designated Service Area**

| OPO | Transplant Center |
|---|---|
| Transplant Resource Center of Maryland | • Johns Hopkins Hospital, Baltimore, MD<br>• University of Maryland Medical Center, Baltimore, MD |
| Washington Regional Transplant Consortium | • Children's National Medical Center, Washington, DC<br>• George Washington University Medical Center and VA Medical Center*, Washington, DC<br>• Georgetown University Medical Center, Washington, DC<br>• Howard University Hospital, Washington, DC<br>• Walter Reed Army Medical Center*, Washington, DC<br>• Washington Hospital Center, Washington, DC<br>• Warren Grant Magnuson Clinical Center/National Institutes of Health*, Bethesda, MD<br>• Inova Fairfax Hospital, Falls Church, VA |

Source: UNOS OPTN Data as of September 5, 2000.
Note: * federal hospital.

## *B. Utilization Trends*

### *Supply and Utilization of Transplant Programs*

The number of solid organ transplant centers in the UNOS registry has changed very little over the past decade (Table 3). Each center has a separate program for each type of organ transplantation it offers. The number of transplant programs has increased by more than 25% over the period from 1990 to 2000. Transplant centers have moved from having 2.2 organ transplant programs on average in 1990 to 2.7 in 2000.

**Table 3: Number of Centers with Active Solid Organ Transplant Programs Registered with UNOS: United States, 1990-2000**

| Category | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Number of Centers** | 255 | 255 | 256 | 263 | 267 | 265 | 267 | 265 | 263 | 266 | 264 |
| **Number of Programs** | 556 | 577 | 619 | 653 | 687 | 690 | 703 | 691 | 689 | 699 | 705 |

Source: UNOS OPTN Data as of July 2001.

Table 4 shows the growth in the number of transplants performed in the U.S. since 1990. Combined kidney-pancreas and heart-lung transplants are reported in their own rows. Other multi-organ transplants are reported in each organ-specific row. For example, a kidney-liver transplant would be reported in both the kidney transplant activity row and the liver transplant activity row.

The number of solid organ transplants performed in the United States from 1990 to 1999 has increased approximately 45 percent. Heart-lung transplant procedures peaked in 1994 with 71 cases and have since declined. Intestine and pancreas transplants have experienced the greatest percentage increase in procedures over the ten-year period.

**Table 4: Trends in the Utilization of Solid Organ Transplant Programs: United States, 1990-September 2000**

| Program | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000* |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Kidney** | 9,416 | 9,674 | 9,737 | 10,357 | 10,644 | 11,048 | 11,360 | 11,676 | 12,365 | 12,493 | 9,738 |
| **Pancreas** | 69 | 78 | 64 | 113 | 94 | 107 | 164 | 208 | 245 | 362 | 314 |
| **Kidney-Pancreas** | 459 | 452 | 492 | 661 | 748 | 918 | 860 | 852 | 972 | 930 | 729 |
| **Liver** | 2,690 | 2,953 | 3,064 | 3,441 | 3,651 | 3,925 | 4,070 | 4,177 | 4,503 | 4,696 | 3,708 |
| **Heart** | 2,107 | 2,126 | 2,171 | 2,297 | 2,340 | 2,361 | 2,346 | 2,293 | 2,345 | 2,182 | 1,739 |
| **Lung** | 203 | 405 | 535 | 668 | 722 | 872 | 814 | 930 | 864 | 877 | 748 |
| **Heart-Lung** | 52 | 51 | 48 | 60 | 71 | 69 | 39 | 62 | 47 | 49 | 31 |
| **Intestine** | 5 | 12 | 22 | 34 | 23 | 45 | 45 | 68 | 68 | 70 | 53 |
| **Total** | **15,001** | **15,751** | **16,133** | **17,631** | **18,293** | **19,345** | **19,698** | **20,266** | **21,409** | **21,659** | **17,060** |

Data on intestine transplants was not collected prior to April, 1994. At that time, information was collected retrospectively for transplants performed January, 1990 - March, 1994.
Source: UNOS: Based on OPTN data as of November 27, 2000.
* Note: Data reported is for the 9-month period, January – September 2000, the most recent data for individual program types.

Table 5 shows the growth in the number of solid organ transplants performed in the Maryland and Washington regions since 1990. There has been a 200 percent increase in the utilization of solid organ transplants in the last decade, a much greater rate of increase than the national increase of 44 percent during the same period.

Heart-lung transplants in the local regions have experienced a decline. Pancreas and liver transplants have experienced the greatest percentage increase in procedures over the past ten years.

**Table 5: Trends in the Utilization of Solid Organ Transplant Programs: Maryland & Washington Regions, 1990-1999**

| Program | Regional Service Area | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Kidney** | **MD** | 91 | 111 | 149 | 194 | 204 | 239 | 267 | 311 | 375 | 493 |
| | **Wash** | 174 | 213 | 216 | 178 | 197 | 198 | 208 | 181 | 247 | 299 |
| | **Total** | **265** | **324** | **365** | **372** | **401** | **437** | **475** | **492** | **622** | **792** |
| **Pancreas** | **MD** | 0 | 0 | 6 | 9 | 18 | 16 | 46 | 51 | 41 | 80 |
| | **Wash** | 0 | 0 | 0 | 0 | 0 | 0 | 4 | 3 | 7 | 4 |
| | **Total** | **0** | **0** | **6** | **9** | **18** | **16** | **50** | **54** | **48** | **84** |
| **Kidney-Pancreas** | **MD** | 0 | 9 | 20 | 25 | 22 | 55 | 45 | 28 | 34 | 21 |
| | **Wash** | 22 | 17 | 28 | 26 | 30 | 24 | 23 | 21 | 27 | 12 |
| | **Total** | **22** | **26** | **48** | **51** | **52** | **79** | **68** | **49** | **61** | **34** |
| **Liver** | **MD** | 37 | 43 | 54 | 54 | 62 | 67 | 74 | 70 | 80 | 76 |
| | **Wash** | 0 | 1 | 11 | 19 | 32 | 41 | 59 | 41 | 44 | 57 |
| | **Total** | **37** | **44** | **65** | **73** | **94** | **108** | **133** | **111** | **124** | **133** |
| **Heart** | **MD** | 18 | 21 | 22 | 25 | 17 | 36 | 32 | 21 | 25 | 27 |
| | **Wash** | 30 | 35 | 25 | 42 | 36 | 30 | 33 | 23 | 27 | 23 |
| | **Total** | **48** | **56** | **47** | **67** | **53** | **66** | **65** | **44** | **52** | **50** |
| **Lung** | **MD** | 0 | 0 | 2 | 4 | 5 | 17 | 29 | 14 | 27 | 33 |
| | **Wash** | 0 | 1 | 1 | 2 | 6 | 2 | 4 | 3 | 10 | 13 |
| | **Total** | **0** | **1** | **1** | **6** | **11** | **19** | **33** | **17** | **37** | **46** |
| **Heart-Lung** | **MD** | 3 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 1 |
| | **Wash** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| | **Total** | **3** | **0** | **0** | **0** | **0** | **0** | **1** | **1** | **0** | **1** |
| **All Solid Organs** | **Total** | **375** | **451** | **532** | **578** | **629** | **725** | **825** | **768** | **944** | **1,140** |

Source: 2000 OPTN/SR AR 1990-1999. HHS/HRSA/OSP/DOT; UNOS[b].
UNOS Scientific Registry Data as of September 5, 2000.
Includes federal transplant programs.

The International Bone Marrow Transplant Registry (IBMTR) and the Autologous Blood and Marrow Transplant Registry (ABMTR) – North America maintain databases on bone marrow transplant recipients, provide information to physicians, patients and health planning agencies, and coordinate research, based on information submitted on a voluntary basis from over 400 transplant centers in 47 countries. IBMTR/ABMTR reports the use of stem cell transplants to be increasing in the United States for data available from 1975 to 1998.

MHCC surveys bone marrow transplant centers within the two regional service areas to monitor utilization of autologous and allogeneic bone marrow transplant programs. Survey data is available from 1998 to first quarter 2001.

Utilization of stem cell transplantation in hospitals in the Maryland and Washington regions had been steadily increasing; however, autologous transplants had a 17 percent decrease from 1998 to 1999 (Table 6). This dramatic drop after steady growth is most likely due to disappointing preliminary results in several recent autologous trials in breast cancer.

Although there was an average 9 percent increase per year from 1997 to 1999 for allogeneic transplants, there are indications that there is a leveling off of allogeneic transplants mainly due to limited availability of human leukocyte antigen (HLA)-matched donors, limited success to date with more disparate donors and a slower expansion into new diagnoses.

**Table 6: Trends in the Utilization of Stem Cell Transplant Programs: Maryland & Washington Regions, 1997-1999**

| Stem Cell | Regional Service Area | 1997 | 1998 | 1999 |
|---|---|---|---|---|
| **Autologous** | **MD** | 218 | 241 | 225 |
| | **Wash** | 134 | 166 | 114 |
| | **Total** | **352** | **407** | **339** |
| **Allogeneic** | **MD** | 81 | 103 | 113 |
| | **Wash** | 33 | 27 | 22 |
| | **Total** | **114** | **130** | **135** |
| **All Stem Cell** | **Total** | **466** | **537** | **474** |

Sources: Maryland Discharge Abstract Data, DC Discharge Data, Fairfax Hospital, as of July 2001.

Appendix B shows the utilization of individual transplant programs operating in the Maryland and Washington regions.

### *Supply of Organs*

The demand for solid organ transplantation, as measured by the number of registrants on the waiting list on December 31st of each year, increased 250 percent from 1990 to 2000. However, the number of transplants performed grew only by 52 percent over the same time period. This disparity between utilization and potential demand is due to the limited organ supply rather than the capacity of transplant centers. The gap between demand and organ supply continues to widen.

The number of donors has grown by 75 percent nationally over the stated years; this increase can be attributed mainly to the increase in living donors (164 percent increase from 1990 to 2000).

**Table 7: National Trends for Solid Organs, 1990-2000**

| Classification | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 | 2000 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Waiting List | 21,914 | 24,719 | 29,415 | 33,394 | 37,684 | 44,066 | 50,252 | 56,772 | 64,473 | 72,110 | 77,330 |
| Transplants Performed | 15,001 | 15,751 | 16,133 | 17,631 | 18,293 | 19,345 | 19,698 | 20,266 | 21,409 | 21,659 | 22,854 |
| Living Donors | 2,124 | 2,425 | 2,572 | 2,906 | 3,102 | 3,458 | 3,756 | 4,021 | 4,496 | 4,748 | 5,600 |
| Cadaveric Donors | 4,509 | 4,526 | 4,520 | 4,861 | 5,100 | 5,359 | 5,416 | 5,477 | 5,799 | 5,822 | 5,984 |

Source: UNOS OPTN data as of April 7, 2001.

The number of cadaveric donors has increased 33 percent over the period from 1990 to 2000. Cadaveric donors are able to supply multiple organs, and the actual availability of cadaveric organs has increased 41 percent over the same time period. In 1999, one cadaveric donor provided on average 3.6 organs, of which 1.8 were kidneys (Table 8).

**Table 8: Rate of Organ Recovery per Cadaveric Donor: United States, 1990-1999**

| Year | Number of Cadaveric Donors | Number of Cadaveric Organs | Rate of Organ Recovery per Cadaveric Donor: Kidney | Liver | Pancreas | Heart | Lung | Intestine | All Organs |
|---|---|---|---|---|---|---|---|---|---|
| **1990** | 4,509 | 15,002 | 1.90 | 0.64 | 0.21 | 0.48 | 0.10 | 0.00 | 3.33 |
| **1991** | 4,526 | 15,603 | 1.87 | 0.70 | 0.24 | 0.49 | 0.15 | 0.00 | 3.45 |
| **1992** | 4,520 | 16,038 | 1.88 | 0.74 | 0.22 | 0.50 | 0.21 | 0.00 | 3.55 |
| **1993** | 4,861 | 18,108 | 1.89 | 0.77 | 0.26 | 0.50 | 0.30 | 0.01 | 3.73 |
| **1994** | 5,100 | 19,267 | 1.87 | 0.80 | 0.27 | 0.50 | 0.33 | 0.01 | 3.78 |
| **1995** | 5,359 | 19,774 | 1.85 | 0.81 | 0.24 | 0.47 | 0.30 | 0.02 | 3.69 |
| **1996** | 5,416 | 19,706 | 1.85 | 0.82 | 0.24 | 0.46 | 0.26 | 0.01 | 3.64 |
| **1997** | 5,477 | 20,056 | 1.84 | 0.84 | 0.24 | 0.44 | 0.28 | 0.01 | 3.66 |
| **1998** | 5,799 | 20,829 | 1.83 | 0.84 | 0.25 | 0.42 | 0.24 | 0.01 | 3.59 |
| **1999** | 5,822 | 21,155 | 1.84 | 0.85 | 0.28 | 0.40 | 0.25 | 0.02 | 3.63 |

Source: UNOS OPTN data as of September 5, 2000.

Strategies are in place to increase organ donation nationwide. The National Organ and Tissue Donation Initiative launched in December 1997 seeks to increase donation through:

- encouraging more individuals to choose to be organ donors and to share that decision with their families;
- improving performance by hospitals and OPOs toward ensuring that the families of potential donors are given the opportunity to allow donation, and fostering higher consent rates by families; and
- conducting research on enhancing donation.

Maryland residents also suffer from limited organ supply, although not as severely as the national experience. There were 1,126 transplants performed in the two regions throughout 2000 (UNOS as of July 13, 2001, excluding federal hospitals). The two regions serving Maryland residents have a combined waiting list of approximately 3,561 (as of May 2001, TRC; and as of June 2001, WRTC).

After declining from 1995 to the end of 1997, cadaveric donations began to increase again in 1998 for the regions (Table 9). This positive improvement in organ donation can be partly attributed to the William H. Amoss Organ and Tissue Donation Act, which was enacted by the Maryland General Assembly in April 1998.

**Table 9: Cadaveric Donors Procured by Selected OPOs: 1990-1999**

| OPO | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 |
|---|---|---|---|---|---|---|---|---|---|---|
| Transplant Resource Center of Maryland | 52 | 62 | 65 | 68 | 59 | 76 | 66 | 52 | 68 | 78 |
| Washington Regional Transplant Consortium | 63 | 68 | 77 | 73 | 84 | 74 | 82 | 65 | 67 | 91 |
| **Total** | **115** | **130** | **142** | **141** | **143** | **150** | **148** | **117** | **135** | **169** |

Source: UNOS OPTN Data as of September 5, 2000.

The Washington Regional Voluntary Living Donor Registry, a partnership between the Washington Regional Transplant Consortium and seven Washington-area kidney transplant programs, has recently launched a new program with the aim of making more kidneys available to patients needing transplants. The growing transplant waiting list prompted WRTC and the transplant programs at Children's National Medical Center, Georgetown University Medical Center, Howard University Hospital, Inova Fairfax Hospital, National Institutes of Health (NIH), Walter Reed Army Medical Center and Washington Hospital Center to create the registry as an innovative way to increase the supply of organs.

The program, known as *Hope Through Sharing*, allows a person waiting for a kidney transplant to take a higher priority on the list when a relative makes a living donation to another waiting recipient. If a living donor is not blood compatible with a relative awaiting transplant, but is willing to donate, then the donor can give to a matched person on the waiting list. The relative, in turn, would move to that person's position. While the program gives an advantage to people on the waiting list that know willing donors, everyone benefits in the end. The waiting list for transplants is reduced which means everyone gets closer to the option of a transplant and someone on the waiting list is given an organ by a living donor (living donor organs outlast cadaveric organs on average).

New medical and scientific developments are also playing a role in decreasing the gap between need and supply by improving supply issues, for example, by increasing organ viability and reducing recovery time for living donors. Living donors are increasingly used for kidney and liver transplants, and have had a significant impact on increasing the supply of those organs.

However, there have also been factors that have decreased the organ supply. Organ donation has failed to increase at a greater rate, in large part due to a significant increase in human immunodeficiency virus (HIV) and hepatitis C virus (HCV) infection resulting in non-viable organs. Furthermore, there has been a decrease in the number of deaths from motor vehicle accidents due to State laws requiring helmets for motorcyclists and imposing stricter penalties for drunk driving, and general advances in automobile safety.

### *Demand for Organs*

New medical and scientific developments are playing a role in decreasing the gap between need and supply by potentially decreasing demand, for example, decreasing the need for re-transplantation, improving disease prevention and health promotion, and providing alternative treatments for organ failure.

Organ failure, leading to the need for organ transplantation, often is the result of preventable disease. Therefore, it is hoped that the demand for some organ transplants will decrease over time with the increase in focus on health promotion and disease prevention, so that patients do not reach the point of end-stage organ failure.

The most common risk factors leading to the need for kidney, pancreas, liver, heart and lung transplants are chronic heavy alcohol use, obesity, diabetes mellitus, hypertension and smoking.

Data from the Behavioral Risk Factor Surveillance System (BRFSS), Table 10, shows that Maryland residents have not been effective in reducing major risk factors known to lead to conditions that may result in end-stage organ failure.

Maryland residents have reported varied levels of chronic drinking over the years; the percentage peaked at 4.1 percent in 1999, the most recent year for which data is available.

Adults reporting to be current smokers have remained relatively constant over the years 1990 to 2000 for the nation (23.0 and 23.2 percent, respectively), although Maryland residents reported a decline from 1990 to 2000 (22.0 compared to 20.5 percent).

The BRFSS data indicate that the prevalence of adult obesity has been increasing. The nationwide median rose from 11.6 percent in 1990 to 20.1 percent in 2000. Maryland's rate similarly increased from 12 percent in 1990 to 20.2 percent in 2000.

**Table 10: Self-Reported Rates of Chronic Drinking, Smoking and Obesity: Maryland and United States, 1990-2000**

| Year | Alcohol Use: Chronic Drinking* | | Current Smokers † | | Obesity: Body Mass Index‡ | |
|---|---|---|---|---|---|---|
| | Maryland % | Nationwide % | Maryland % | Nationwide % | Maryland % | Nationwide % |
| **1990** | 1.7 | 3.2 | 22.0 | 23.0 | 12.0 | 11.6 |
| **1991** | 3.2 | 3.4 | 21.7 | 23.1 | 11.6 | 12.6 |
| **1992** | 2.5 | 3.0 | 20.0 | 22.2 | 12.6 | 12.6 |
| **1993** | 1.9 | 3.0 | 19.8 | 22.6 | 13.9 | 13.7 |
| **1994** | - | - | 20.2 | 22.7 | 14.7 | 14.4 |
| **1995** | 2.3 | 2.8 | 21.3 | 22.4 | 16.3 | 15.8 |
| **1996** | - | - | 20.9 | 23.4 | 17.7 | 16.8 |
| **1997** | 1.2 | 3.0 | 20.4 | 23.2 | 17.5 | 16.6 |
| **1998** | - | - | 22.4 | 22.9 | 20.5 | 18.3 |
| **1999** | 4.1 | 3.6 | 20.3 | 22.6 | 18.2 | 19.7 |
| **2000** | - | 4.5 | 20.5 | 23.2 | 20.2 | 20.1 |

Source: CDC Behavioral Risk Factor Surveillance System. http://apps.nccd.cdc.gov/brfss/Trends/TrendData.asp (accessed July 25, 2001).
State % = Weighted Percentage.
Nationwide % - is the median weighted percentage for states surveyed.
*Chronic Drinkers: All respondents 18 and older who report an average of two or more drinks per day i.e., 60 or more alcoholic drinks a month.
†Smokers: All respondents 18 and older who have ever smoked 100 cigarettes in their lifetime and reported smoking every day or some days.
‡Obesity: All respondents 18 and older who report that their Body Mass Index (BMI) is 30.0 or more. BMI is defined as weight in kilograms divided by height in meters squared ($w/h^2$).
Denominator includes all survey respondents except those with missing, don't know, and refused answers.
-: survey data not collected.

Age-adjusted mortality data for 1997 to 1999 (Table 11) indicate that Maryland has had a slight decline in deaths due to diabetes mellitus, while the nation has been increasing. However, the age-adjusted death rate for diabetes mellitus in Maryland remains higher than the national rate. The age-adjusted death rate for chronic liver disease and cirrhosis were similar in 1999 for Maryland and the nation, however, Maryland's trend is increasing, while the nation is showing a decrease in deaths.

**Table 11: Age-Adjusted Death Rates per 100,000 Population for Diabetes Mellitus and Chronic Liver Disease: Maryland and United States, 1997-1999**

| | Age-Adjusted Death Rate* | | | | | |
|---|---|---|---|---|---|---|
| | Diabetes Mellitus | | | Chronic Liver Disease & Cirrhosis | | |
| | 1997 | 1998 | 1999 | 1997 | 1998 | 1999 |
| **Maryland** | 30.7 | 31.2 | 29.7 | 8.7 | 9.2 | 9.5 |
| **United States** | 24.1 | 24.4 | 25.2 | n/a | 9.9 | 9.7 |

Sources: Division of Health Statistics. Maryland Department of Health and Mental Hygiene, Maryland Vital Statistics Annual Report, 1999. National Vital Statistics Report. Deaths: Preliminary Data for 1999. Vol 49. No 3. June 26, 2001.
*Death rates are age-adjusted to the 2000 projected U.S. population.
n/a – data not available.

## *Recent Anticipated Clinical Advances*

Recent anticipated clinical advances in transplantation could change practice and success rates. These include the following[1]:

• **Split Liver Transplantation**. Under this procedure, a whole adult cadaveric liver is divided into two functioning allografts. Each portion is transplanted into a different patient. Once transplanted, the liver allograft regenerates until it becomes, essentially, a whole liver. (The liver is one of the few organs or systems in the human body that can regenerate in this way.) Split livers are in effect a practical means of expanding the donor pool. At present, clinical judgment is that about 15 to 25 percent of the available cadaveric donors may be suitable for splitting.

• **Live Donors of Livers**. Relying on the liver's unique ability to regenerate itself, recently it has been found feasible to cut away the right lobe of the liver (about half of its total size) in a living donor, transplant the lobe to a recipient and have both patients regenerate a whole, healthy liver. An advantage of this procedure is that it allows the timing of the transplantation to be determined based on the recipient's current health status and prognosis, rather than on the arbitrary date on which a cadaveric organ might become available. Some predict that living donors will become as important to liver transplantation as living donors are to kidney transplantation.

• **Live Donor Laparoscopic Nephrectomy**. Living donors have long been a generous source for kidneys. Because only one of the body's two kidneys is needed to perform the organ's functions, most persons can donate one kidney with only a very small risk to the donor's long-term health. Living donor kidneys have less delayed graft function, shorten the transplant candidate's wait, allow for advance planning of the procedure, have less cold ischemia, may allow better human leukocyte antigen (HLA) matching, may allow preoperative initiation of immunosuppression, have lower incidence of early acute rejection, and have improved graft and patient survival rates. Compared to open nephrectomy, the procedure traditionally employed to recover a kidney from a living donor, laparoscopic donor nephrectomy results in shorter hospital stay, shorter convalescence, less pain and less disfigurement. Laparoscopic nephrectomy is becoming more widely accepted and used, as the surgical technique has improved, as transplant surgeons have gained experience performing these procedures and as favorable donor and recipient outcomes have been obtained.

• **Pancreas and Islet Cell Transplantation**. Whole organ pancreas transplantation, when successful, eliminates insulin dependence and restores normoglycemia in diabetics, improves quality of life and may stabilize neuropathy. However, the procedure is risky and there is a high rate of complication. Clinical trials of pancreatic islet cell transplantation are in progress. Islet cell transplantation is easier to perform but is still considered experimental, with few such procedures having been performed and with little data on outcomes. Both whole pancreas and islet cell transplantation require life-long immunosuppression. Combined kidney-pancreas transplantation, a procedure being performed in increasing numbers, is a complex procedure, and may require higher levels of immunosuppression and result in greater morbidity than kidney transplant alone.

• **Liver Assist Systems**. Two liver assist systems utilizing hepatocytes are currently undergoing clinical trials in the United States. The Food and Drug Administration (FDA) regulates these systems as biologics, not devices, since exogenous substances are released and endogenous substances are biotransformed by the hepatocytes.

1) The HepatAssist 2000 is a bioartificial liver system that uses plasma separation and porcine hepatocytes located in a hollow fiber cartridge. Phase I clinical trials showed success in bridging fulminant hepatic failure patients to transplantation or recovery and patients with primary graft non-function to retransplantation. Safety concerns exist related to immunologic risks posed by exposure to porcine proteins and the potential for transmitting infectious disease from animals.
2) The Hepatix extracorporeal liver-assist device (ELAD) uses the C3A/HepG2 human hepatoblastoma cell line. It was shown to have no short-term safety problems in a non-controlled phase I clinical trial and in a pilot-controlled trial. However, in the pilot-controlled trial, survival advantage of the ELAD treated group was not demonstrated for either transplant or non-transplant candidates. Also, the use of hepatocytes derived from a tumor cell line raises safety concerns.

• **Cardiac Assist Devices**. Several devices are currently in use as bridges to cardiac transplantation and even as alternatives to transplantation. Most of these devices are activated pneumatically or use an electrical power source.

1) The Abiomed Ventricular Assist Device (VAD), the first FDA-approved heart-assist device, was approved in 1992 for use in postcardiotomy patients but has also been used as a bridge to transplantation.
2) The Thoratec VAD was approved by the FDA in 1995 for use in the hospital as a bridge to transplantation for cardiac transplant patients at risk of imminent death.
3) The HeartMate VAD was approved by the FDA in 1994 for use in hospitals as a bridge to transplantation.
4) The HeartMate Vented Electric Left Ventricular Assist System (LVAS) and the Novacor LVAS portable heart-assist devices were both approved by the FDA in September 1998 for use outside of the hospital by patients awaiting heart transplants. These devices are also being used for permanent implantation (without intention to transplant) and may provide a viable alternative for patients who become unsuitable for transplantation.
5) The CardioWest total artificial heart (TAH) is a pneumatic device used as a bridge to transplantation. It is the only TAH available that totally replaces the failing ventricles. This device debuted in the early 1980s as a permanent device called the Jarvik-7 TAH,

then was used as a bridge to transplantation under the name Symbion TAH in the mid 1980s. It lost its investigational device exemption (IDE) in 1990 due to failure of the manufacturer to comply with IDE regulations. The same device was renamed and began clinical trials at selected centers in the United States in 1993 (under a new FDA IDE). A controlled trial found improved survival in the CardioWest implant group compared to controls.

• **Xenotransplantation.** The use of organs, tissues, or cells from non-human animals has the potential not only for treating organ failure in humans, but also for treating a variety of diseases for which transplantation has not been a traditional tool. The term "xenotransplantation" is also used to include procedures in which non-human organs, tissues or cells are used for *ex vivo* contact with human body fluids, cells, tissues or organs that are subsequently given to a human recipient. An example of the clinical application of xenotransplantation in the treatment of end-stage organ disease is the use of porcine hepatocytes in the extracorporeal liver assist system. The FDA has authorized no clinical investigations for whole organ xenotransplants. Currently, all xenotransplantation protocols are either cellular implants, *ex vivo* exposures or extracorporeal perfusion. A major challenge in xenotransplantation is overcoming immunologic barriers--particularly the hyperacute rejection that occurs with vascularized organs. One future avenue is transplantation of organs from transgenic pigs. Basic research has explored insertion of human genes into porcine DNA to create a line of pigs from which organs can be obtained that will not be as vulnerable to rejection to the human immune system.

# III. Organ Transplant Services: An Examination of Regulatory Issues and Policy Options

## *A. Categories of Covered Transplant Programs*

The federal Department of Health and Human Services (DHHS) has directed UNOS, the OPTN contractor, to consider and recommend to DHHS those organs or parts of organs that should be subject to the policies of the OPTN. The current rules governing the OPTN define "organ" as a human kidney, liver, heart, lung or pancreas. DHHS has also appointed an advisory committee on organ transplantation to provide independent advice on the policies developed by the national OPTN.

Medicare currently covers kidney, heart, lung, heart-lung, liver and intestinal transplantation. Medicare will also cover whole organ pancreas transplantation only when it is performed simultaneously with or after a kidney transplant. Medicare currently excludes coverage of transplantation of partial pancreatic tissue or islet cells.

The current Maryland State Health Plan requires a separate CON for the development of a new transplant program in each of the categories listed in Table 12, whether or not the institution has another transplant program.

During the promulgation of the current regulations for the State Health Plan: Specialized Health Care Services – Organ Transplant Services, much discussion was held over the inclusion or exclusion of autologous stem cell transplants. It was decided, after considerable research and consultation with experts in the field, that stem cell transplantation is a highly specialized, expensive and volume-sensitive transplant procedure and hence appropriate for regionalization and inclusion in the regulations governing organ transplant services.

**Table 12: Categories of Transplant Programs Currently Covered in COMAR 10.24.15**

| | |
|---|---|
| Solid Organ Programs | Kidney<br>Pancreas<br>Liver<br>Heart<br>Lung<br>Heart/Lung<br>Intestine (Small Bowel)<br>Others, to be determined by the Commission as needed |
| Hematopoietic Stem Cell (Bone Marrow) Programs | Autologous<br>Allogeneic |
| Other Transplantable Cells | Islet Cells<br>Hepatocytes<br>Others, to be determined by the Commission as needed |

Source: COMAR 10.25.15.

#### ♦ Option 1: Current Categories of Transplant Programs

Maintain Policy 1 of the current plan, which states that "for the purposes of regulation organ transplantation refers to the major solid organs (kidney, liver, pancreas, heart and lung), intestine or small bowel, hematopoietic stem cells, and other transplantable cells." This definition is consistent with the policies of UNOS and the Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT). The Technical Advisory Committee on Organ Transplants and the Technical Advisory Committee on Stem Cell Transplantation both recommended that autologous and allogeneic hematopoietic stem cell and bone marrow transplants programs are specialized services and therefore appropriate for inclusion.

A standard in the Plan requires that an applicant for a non-established organ transplant program or other cellular transplant program (for example, pancreatic islet cells) shall demonstrate its ability to meet all requirements of a new transplant program for the related organ (for example, pancreas). If an applicant has an established transplant program in the related solid organ that meets minimum volume requirements, a full CON review should not be necessary for the cellular transplant program.

#### ♦ Option 2: Additional Categories of Transplant Programs

Although the current plan allows for new developments and their consequential inclusion, it may be appropriate to list additional transplant procedures, such as combined kidney-pancreas transplantation. If new categories are added, national and regional utilization data over a sufficient period of time would be required before the inclusion of need projections and volume standards are made.

## *B. Need Projection Policies*

A major goal of the State Health Plan is to ensure appropriate changes in the capacity of services regulated by the CON program. One of the principal tools used to support this goal is the service-specific need projection methodology. The service-specific need projection methodology is used to determine whether the expected future utilization of a particular service will be sufficient to support new capacity. For organ transplant services, the need projection contains several key components: (1) definition of planning regions; (2) patient migration assumptions; (3) use rate assumptions in projecting future cases; (4) length of planning horizon; and (5) determination of the need for a new program.

### 1. Definition of Planning Regions

While many services addressed in the State Health Plan are suitable for projecting need at the jurisdictional level, for highly specialized services, such as organ transplants, a larger population base is necessary to ensure that programs have adequate caseloads. As a consequence, organ transplant services are planned on a regional basis. Given this consideration, the appropriate geographic regions for analyzing future utilization are an important component of the State Health Plan need projection methodology. Alternative policy options for defining organ transplant service regions are outlined in Table 13.

### ♦ Option 1: Regional Service Areas Consistent with OPO Regions

Maintain current regional service areas for planning organ transplant services: Maryland and Washington regions. The two regions used in the current plan reflect regions designated by UNOS per CMS in 1999.

CMS designates the Organ Procurement Organizations (OPO) service area by assigning counties to specific OPOs. The assignment is regularly reviewed on the basis of population need. OPOs may negotiate with other OPOs for specific counties. CMS must approve these waivers and special assignments that permit a hospital to have an arrangement with a different OPO than the one assigned to its service area.

CMS policies also include provisions to modify these service areas. If an OPO wishes to change its service area or merge, it must submit new certification forms. In addition, two or more OPOs may enter into a sharing arrangement, that is, an arrangement to share organs, interregionally or intraregionally, between or among the OPOs. OPOs may distribute organs pursuant to a sharing arrangement with the prior approval of the UNOS Board of Directors. Organs must be distributed within the sharing area on the basis of a common Patient Waiting List.

The OPOs covering the two regions are the Transplant Resource Center of Maryland (TRC) and the Washington Regional Transplant Consortium (WRTC). TRC provides service to people living in Maryland, excluding Charles, Montgomery and Prince George's counties. WRTC serves Washington, D.C., suburban Maryland and Northern Virginia.

### ♦ Option 2: Regional Service Areas Excluding Out-of-State Areas

Another approach would be to create two regions, excluding the out-of-state components. One region may consist of Western and Central Maryland with the second region being made up of Southern and Eastern Maryland. Defining service areas as only in Maryland may have a negative impact on travel time for some residents. The regionalization of the procurement of organs by the OPO would continue.

**Table 13: Comparison of Alternative Options for Defining Organ Transplant Planning Regions**

| Option | Region 1 | Region 2 |
|---|---|---|
| **Option 1:**<br>Current Planning Regions – OPO Regional Service Areas | **Maryland Region**<br>All Maryland counties excluding Charles, Montgomery and Prince George's counties | **Washington Region**<br>Charles County<br>Montgomery County<br>Prince George's County<br>Washington, D.C.<br>Northern Virginia |
| *Population*<br>*Transplant Centers*<br>*Solid/Stem Cell* | *3,341,503*<br><br>*2/4* | *4,187,358*<br><br>*5/6* |
| **Option 2:**<br>Regional Service Areas Excluding Out-of-State Areas | **Western & Central Maryland**<br>Anne Arundel County<br>Baltimore City<br>Baltimore County<br>Harford County<br>Howard County<br>Allegany County<br>Carroll County<br>Frederick County<br>Garrett County<br>Washington County<br>Montgomery County | **Southern & Eastern Maryland**<br>Calvert County<br>Charles County<br>Prince George's County<br>St. Mary's County<br>Caroline County<br>Cecil County<br>Dorchester County<br>Kent County<br>Queen Anne's County<br>Somerset County<br>Talbot County<br>Wicomico County<br>Worcester County |
| *Population*<br>*Transplant Centers*<br>*Solid/Stem Cell* | *3,653,603*<br><br>*2/4* | *1,432,863*<br><br>*0/1* |

Source: Population Data: MD – Data June 1999 Md Dept. of Planning, with Feb. 2000 update; DC – US Census; VA – Virginia Employment Commission, August 24, 1999.

## 2. Patient Migration Patterns

Another key policy assumption in the current methodology used to forecast projected organ transplant cases concerns patient in- and out-migration patterns. Highly specialized services, such as organ transplants, often encourage migration due to the services being concentrated in a small number of hospitals, and requiring patients routinely to cross jurisdictional as well as state boundaries to receive this care.

For example, Medicare will cover intestinal transplantation only if performed in an approved center. As of May 1, 2001, the list of Medicare-approved intestinal transplant centers included the following: University of Pittsburgh Medical Center in Pittsburgh, Pennsylvania; Mount Sinai Hospital in New York, New York; University of Miami, Jackson Memorial Hospital, in Miami, Florida; and Nebraska Health System in Omaha, Nebraska.

### ♦ Option 1: Constant Patient Migration Patterns Between Base and Target Years

Maintain the plan assumption that existing patient migration patterns will remain constant between the base and target years of the forecast for each transplant type. The migration patterns of patients using transplant services in the two regional service areas and in other states remain unchanged in the target year.

### ♦ Option 2: Changes in Migration Patterns Between Base and Target Years for the State of Maryland

A second option would be to adjust the in- and out-migration patterns. In-migration may be changed to refer to persons receiving organ transplant services in Maryland hospitals that lived outside the state; out-migration may be redefined as persons who lived within the State of Maryland and left Maryland to receive care. This option would result in adjusted retention rates.

Table 14 and Table 15 show the percentages of in-migration into Maryland services and out-migration of Maryland residents to transplant services in other states. Out-migration of Maryland residents is mainly to the District of Columbia and Northern Virginia, both of which are within the Washington region.

**Table 14: In-Migration: Utilization by Out-of-State Patients of Transplant Programs in Maryland: 1996-2000**

| Year | Transplant Program | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Kidney | | Pancreas | | Liver | | Heart | | Lung | | Heart-Lung | |
| | % | n | % | n | % | n | % | n | % | n | % | n |
| 1996 | 33 | 104 | 51 | 46 | 16 | 12 | 19 | 6 | 38 | 11 | - | - |
| 1997 | 32 | 107 | 38 | 29 | 17 | 12 | 33 | 7 | 36 | 5 | - | - |
| 1998 | 39 | 157 | 59 | 44 | 19 | 15 | 36 | 9 | 44 | 12 | - | - |
| 1999 | 33 | 168 | 60 | 58 | 36 | 27 | 33 | 9 | 45 | 15 | 100 | 1 |
| 2000 | 33 | 195 | 45 | 34 | 26 | 21 | 43 | 9 | 32 | 8 | 100 | 2 |

Source: UNOS, data as of July 13, 2001.

**Table 15: Out-Migration: Utilization by Maryland Residents of Other States' Transplant Programs: 1996-2000**

| Year | Transplant Program | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Kidney | | Pancreas | | Liver | | Heart | | Lung | | Heart-Lung | |
| | % | n | % | n | % | n | % | n | % | n | % | n |
| 1996 | 33 | 101 | 23 | 13 | 34 | 32 | 47 | 23 | 25 | 6 | - | - |
| 1997 | 27 | 86 | 21 | 13 | 33 | 28 | 58 | 19 | 25 | 3 | 100 | 1 |
| 1998 | 34 | 128 | 43 | 23 | 33 | 32 | 53 | 18 | 25 | 5 | - | - |
| 1999 | 26 | 119 | 15 | 7 | 35 | 26 | 44 | 14 | 22 | 5 | - | - |
| 2000 | 24 | 129 | 14 | 7 | 43 | 45 | 43 | 9 | 37 | 10 | 100 | 1 |

Source: UNOS, data as of July 13, 2001.

## 3. Use Rate Assumptions in Projecting Future Cases

Assumptions about future use rates, or the expected volume of cases per 100,000 population, are a key component of the need projection methodology. Detailed tables on the impact of the assumptions can be found in Appendix C.

### ♦ Option 1: Standard Increase Across Transplant Types for All Ages

Maintain the current methodology for projecting use rates. In the current plan, the base use rate (1997) was calculated from the regional use rates over the five-year period 1992 to 1996 (total organ transplant procedures for the five years 1992 to 1996 divided by the sum of the total population over the same five years). The current plan assumes a 40 percent increase in use rate over the three-year period for the Maryland region to project need in 2000 for all transplant types, except for autologous and allogeneic stem cell transplants, which were projected to increase 60 percent and 30 percent, respectively, over the three-year period. A 20 percent increase in use rate over the three-year period was assumed for the Washington region to project need in 2000 for all transplant types, except for autologous and allogeneic stem cell transplants, which were projected to increase 60 percent and 30 percent, respectively, over the three-year period.

A comparison of the projected 2000 use rates and cases with actual 2000 experience is provided in Table 16. This methodology resulted in two of the five solid organ transplant need projections to be over- or under- estimated by greater than 45 percent for the Maryland region. The Washington region was projected with two out of three transplants being under- or over-estimated by more than 40 percent.

It should be noted that UNOS has changed its reporting methods of kidney and pancreas transplants since the current SHP was written. In the 2000 annual report, UNOS reports such transplants as kidney alone, pancreas alone and combined kidney-pancreas transplants. However, for the purpose of projections and planning, the assumption was made that one combined kidney-pancreas transplant is equivalent to one kidney and one pancreas transplant.

## Table 16: Comparison of Projected and Actual 2000 Use Rates for Solid Organ Transplants

| Transplant Program | | Jurisdiction of Patient | | | |
|---|---|---|---|---|---|
| | | Maryland Region | | Washington Region | |
| | | *Projected* | *Actual* | *Projected* | *Actual* |
| **Kidney** | Use Rates per 100,000 Population | 8.27 | 11.97 | 5.48 | 5.92 |
| | Difference between Projected and Actual Use Rates | 45% | | 8% | |
| | Number of Cases | 277 | 400 | 222 | 248 |
| | Difference between Projected and Actual Cases | 44% | | 12% | |
| **Pancreas** | Use Rates per 100,000 Population | 1.41 | 1.17 | 0.67 | 0.43 |
| | Difference between Projected and Actual Use Rates | -17% | | -36% | |
| | Number of Cases | 47 | 39 | 27 | 18 |
| | Difference between Projected and Actual Cases | -17% | | -33% | |
| **Liver** | Use Rates per 100,000 Population | 1.82 | 2.09 | 1.78 | 1.65 |
| | Difference between Projected and Actual Use Rates | 15% | | -7% | |
| | Number of Cases | 61 | 70 | 72 | 69 |
| | Difference between Projected and Actual Cases | 15% | | -4% | |
| **Heart** | Use Rates per 100,000 Population | 1.06 | 0.51 | 0.88 | 0.53 |
| | Difference between Projected and Actual Use Rates | -52% | | -40% | |
| | Number of Cases | 36 | 17 | 36 | 22 |
| | Difference between Projected and Actual Cases | -53% | | -39% | |
| **Lung** | Use Rates per 100,000 Population | 0.39 | 0.39 | 0.24 | 0.57 |
| | Difference between Projected and Actual Use Rates | 0% | | 139% | |
| | Number of Cases | 13 | 13 | 10 | 24 |
| | Difference between Projected and Actual Cases | 0% | | 140% | |

Sources: Projected data: COMAR 10.24.15, February 2000. Actual data: UNOS, as of July 13, 2001. Population data: MD – Data June 1999 Md Dept. of Planning, with Feb. 2000 update; DC – US Census; VA – Virginia Employment Commission, August 24, 1999.

**Table 17: Comparison of Projected and Actual 1999 Use Rates for Hematopoietic Stem Cell Transplants**

| Transplant Program | | Jurisdiction of Patient | | | |
|---|---|---|---|---|---|
| | | Maryland Region | | Washington Region | |
| | | *Projected* | *Actual* | *Projected* | *Actual* |
| **Autologous Bone Marrow** | Use Rates per 100,000 Population | 5.60 | 4.90 | 4.50 | 2.49 |
| | Difference between Projected and Actual Use Rates | -12% | | -45% | |
| | Number of Cases | 188 | 163 | 182 | 101 |
| | Difference between Projected and Actual Cases | -13% | | -45% | |
| **Allogeneic Bone Marrow** | Use Rates per 100,000 Population | 1.33 | 1.74 | 1.47 | 0.81 |
| | Difference between Projected and Actual Use Rates | 31% | | -45% | |
| | Number of Cases | 45 | 58 | 60 | 33 |
| | Difference between Projected and Actual Cases | 29% | | -45% | |

Sources: Projected data: COMAR 10.24.15, February 2000. Actual data: Maryland Discharge Abstract, DC Discharge Data, HSANV as of July 2001. Population data: MD – Data June 1999 Md Dept. of Planning, with Feb. 2000 update; DC – US Census; VA – Virginia Employment Commission, August 24, 1999.

### ♦ Option 2: Most Recent Three Years of Data to Calculate Average Change for Each Transplant Program

Another option for projecting future use rates is to average the recent 3-year experience (1998-2000) for each region by each transplant type. This method may more accurately reflect the changing trends for each type of transplant procedure.

Base use rate would be determined as in Option 1, but projections would be based on the average percentage change over the same years for each transplant type, and then the rate of change would be compounded between the base year and target year to estimate a projected use rate. Using a shorter 3-year timeframe for baseline data may more accurately reflect recent changes in technologies and developments of organ transplant services.

The use rates for stem cell transplants (autologous and allogeneic) may be under-estimated due to incomplete data on Maryland and Washington regional residents going to facilities outside of the two regional service areas. The use rates for solid organs are more accurate as UNOS is able to provide data for all patients in all regions and all facilities in the United States.

### ♦ Option 3: Constant Base Year Regional Use Rates

An alternative would be to assume a constant use rate, which may be appropriate if the use rate is thought to be leveling off due to decreases in need and/or organ supply. The impact of no change in current use rates on the future volume of cases is illustrated in Appendix C.

### ♦ Option 4: Need projections for two age groups

In addition to basing projections on each transplant type, age-specific use rates may also be used to reflect different usage patterns for pediatric and adult populations. MHCC generally defines

the pediatric population as aged 0-14 years. However, COMAR 10.24.07 defines children and adolescents for the purpose of acute psychiatric services to include individuals aged 0-17 years. In addition, COMAR 10.24.09 defines pediatric services for acute inpatient rehabilitation as less than 18 years of age.

One method would be to define pediatric transplant procedures for the purpose of this chapter as aged less than 18 years, with adults being 18 years or older, which is consistent with data published by UNOS.

According to UNOS, the percentage of pediatric transplant recipients has decreased over time for many organs. However, pediatric thoracic (heart, lung and heart-lung) recipients have increased. Most organ-specific waiting lists for the nation have only a small number of pediatric registrants. In 1998, pediatric registrants accounted for less than 3 percent of the kidney, pancreas, and kidney-pancreas waiting lists. They constituted 6 percent to 7 percent of the liver, heart, and lung waiting lists. In contrast, pediatric registrants accounted for 22 percent of the heart-lung waiting list in 1998. Pediatric registrants, across the nation, had shorter waiting times than adults, in part, because UNOS organ allocation policies show some preference for candidates younger than 18 years of age. The preference is viewed as appropriate because of the unique problems associated with deficits in growth and development and lifelong adverse consequences in this population.

Transplant centers that serve only pediatric patients generally report smaller volumes than centers that serve adults only or both adults and pediatric patients.

**Table 18: Year 2000 Use Rates for Transplants by Age Group: Maryland and Washington Region**

| | | Jurisdiction of Patient | |
|---|---|---|---|
| | **Age Group** | **Maryland Region** | **Washington Region** |
| | | **Population** | |
| | Pediatrics (<18) | 846,823 | 1,043,275 |
| | Adults (18+) | 2,494,680 | 3,144,083 |
| | All Ages | 3,341,503 | 4,187,358 |
| **Organ Type** | | **Use Rates per 100,000 Population** | |
| **Liver** | Pediatrics (<18) | 0.59 | 0.48 |
| | Adults (18+) | 2.61 | 2.05 |
| | All Ages | 2.09 | 1.65 |
| **Heart** | Pediatrics (<18) | 0.24 | 0.19 |
| | Adults (18+) | 0.60 | 0.64 |
| | All Ages | 0.51 | 0.53 |
| **Lung** | Pediatrics (<18) | 0.00 | 0.10 |
| | Adults (18+) | 0.52 | 0.74 |
| | All Ages | 0.39 | 0.57 |
| **Kidney** | Pediatrics (<18) | 0.83 | 0.67 |
| | Adults (18+) | 15.75 | 7.67 |
| | All Ages | 11.97 | 5.92 |
| **Pancreas** | Pediatrics (<18) | 0.00 | 0.00 |
| | Adults (18+) | 1.56 | 0.57 |
| | All Ages | 1.17 | 0.43 |
| **Autologous Bone Marrow** (1999) | Pediatrics (<18) | 0.83 | 0.40 |
| | Adults (18+) | 6.28 | 3.19 |
| | All Ages | 4.90 | 2.49 |
| **Allogeneic Bone Marrow** (1999) | Pediatrics (<18) | 1.54 | 0.79 |
| | Adults (18+) | 1.81 | 0.86 |
| | All Ages | 1.74 | 0.81 |

Source: : Maryland Discharge Abstract, DC Discharge Data, HSANV, Fairfax as of July 2001. Population data: MD – Data June 1999 Md Dept. of Planning, with Feb. 2000 update; DC – US Census; VA – Virginia Employment Commission, August 24, 1999..

**Table 19: Solid Organ Transplant Baseline Use Rates (based on 1998-2000) per 100,000 Population by Age Group and Region**

| Organ Type | Age Group | Jurisdiction of Patient | | | |
|---|---|---|---|---|---|
| | | Maryland Region | | Washington Region | |
| | | Use Rate | Average Change per Yr (%) | Use Rate | Average Change per Yr (%) |
| **Kidney** | Pediatrics (<18) | 1.2 | -27 | 1.2 | -28 |
| | Adults (18+) | 13.0 | 30 | 7.7 | 4 |
| | All Ages | 10.0 | 26 | 6.1 | 2 |
| **Pancreas** | Pediatrics (<18) | 0.0 | - | 0.1 | - |
| | Adults (18+) | 1.4 | 8 | 0.7 | -14 |
| | All Ages | 1.0 | 8 | 0.6 | -18 |
| **Liver** | Pediatrics (<18) | 0.9 | -32 | 0.8 | -32 |
| | Adults (18+) | 2.1 | 10 | 1.9 | 9 |
| | All Ages | 1.8 | 1 | 1.6 | 1 |
| **Heart** | Pediatrics (<18) | 0.1 | - | 0.2 | - |
| | Adults (18+) | 0.9 | -20 | 0.6 | 0.3 |
| | All Ages | 0.7 | -16 | 0.5 | 5 |
| **Lung** | Pediatrics (<18) | 0.2 | - | 0.1 | - |
| | Adults (18+) | 0.6 | -0.5 | 0.5 | 34 |
| | All Ages | 0.5 | -7 | 0.4 | 38 |

Sources: UNOS, data as of July 13, 2001. Population data: MD – Data June 1999 Md Dept. of Planning, with Feb. 2000 update; DC – US Census; VA – Virginia Employment Commission, August 24, 1999.

**Table 20: Stem Cell Transplant Baseline Use Rates (based on 1997-1999) per 100,000 Population by Age Group and Region**

| Stem Cell Type | Age Group | Jurisdiction of Patient | | | |
|---|---|---|---|---|---|
| | | Maryland Region | | Washington Region | |
| | | Use Rate | Average Change per Yr (%) | Use Rate | Average Change per Yr (%) |
| **Autologous Bone Marrow** | Pediatrics (<18) | 0.5 | 8 | 0.3 | 11 |
| | Adults (18+) | 3.7 | 7 | 2.3 | -8 |
| | All Ages | 4.8 | 7 | 3.0 | -8 |
| **Allogeneic Bone Marrow** | Pediatrics (<18) | 0.7 | 42 | 0.5 | -1 |
| | Adults (18+) | 0.8 | 43 | 0.5 | 1 |
| | All Ages | 1.4 | 43 | 0.9 | -2 |

Source: Maryland Discharge Abstract Data, as of July 2001; DC Discharge Data, HSANV, Fairfax Hospital as of July 2001. Population data: MD – Data June 1999 Md Dept. of Planning, with Feb. 2000 update; DC – US Census; VA – Virginia Employment Commission, August 24, 1999.

## 4. Length of Planning Horizon

Another component of the need projection policy involves the length of the planning horizon used to forecast the volume of expected organ transplant cases. The duration of this time period is important because it is a key factor in establishing the framework for re-examination of the plan. While traditionally a five-year planning horizon has been used for chapters of the State Health Plan, for open heart surgery and organ transplant services a shorter, three-year planning horizon has been used.

### ♦ Option 1: Three-Year Planning Horizon

Maintain the current methodology of using a three-year planning horizon. In the current organ transplant services plan, the base year of the need projection is 1997; the target year is 2000. If the same planning horizon is used in the updated plan, the most recent base year data available is 2000, providing a target year of 2003. A shorter planning horizon requires more frequent examination of utilization rates, which reflect actual changes, if any, in the number of organs transplanted.

### ♦ Option 2: Five-Year Planning Horizon

Under the health planning statute, the Commission is required to update the State Health Plan at least every five years. If a five-year planning horizon is used in updating this plan, the base year of the new need projection would be 2000 and the target year 2005. The use of a longer period between the base and target year of the need projection has the potential advantage of providing greater stability with respect to implementing recommendations included in the plan. On the other hand, this longer planning horizon could potentially make it more difficult to adequately consider emerging trends in the organ transplant services.

## 5. Determination of the Need for a New Program

### ♦ Option 1: Current Methodology

Maintain the current methodology to determine need for a new program. In the current plan, an application for a new program will be considered only if both of the following criteria are met:

(1) The difference between the projected transplant cases (3-year planning horizon) and the transplant cases in the current year is greater than the threshold utilization standard; and

(2) All programs meet the State Health Plan minimum utilization standard in the current year.

As a requirement for approving an application for a new program, all existing non-federal programs must be operating at or above the threshold volumes. A new organ transplant program will be approved only if existing programs can maintain at least the threshold volume as a result of the new program. Furthermore, policy 6 of the current Plan states "fewer organ transplant services operating at higher volumes are preferable to more programs at threshold or minimum volumes."

### ♦ Option 2: Revised Methodology

The methodology to determine the appropriateness for a new program could be revised, for example, to consider an application for a new program if the following criteria were met (Appendix D):

(1) The difference between the projected transplant cases (3-year planning horizon) and the transplant cases in the most recent full year of data available is greater than the threshold utilization standard;
(2) All programs of a specific organ type within the region meet or exceed the threshold volume in the most current full year of data available;
(3) There is a positive trend in the utilization of that program type in the region as a whole, over the most recent 3 years of data available; and
(4) The introduction of a new program will not result in a center dropping below the minimum volume standards.

This option may not favor existing low-volume programs over a new program.

## *C. Quality of Care Policies*

In the current SHP, the number of transplants performed annually, status of certification or accreditation by a national organization, and teaching status of the hospital are used as indicators of the quality of care provided by a transplant program. Other indicators of quality are available. For example, UNOS publishes data on actual and expected survival rates at each center.

As the rate of living donation has increased, researchers have begun to study and report the outcomes of living donors, including complications. The federal Agency for Healthcare Research and Quality (AHRQ) recently funded a two-year project designed to improve the care provided to living donors of organs.

### 1. Minimum and Threshold Volume Standards

Research on the relationship between volume of organ transplant procedures and outcome, as measured by mortality and/or complications, reflects a dimension of quality that has received considerable attention in planning for organ transplant services and other specialized health care services.

Research has demonstrated the value of high volumes in a number of specialized services, including organ transplantation, as well as various cardiac care, neonatal intensive care and trauma care[2]. Studies have shown a statistically significant volume-outcome relationship for heart transplantation and bone marrow transplantation; in addition kidney transplantation has shown a non-significant trend towards high volume resulting in better outcome.[3]

Hosenpud et al.[4] found for heart transplantation that the risk of 1-year mortality increased 33 percent in heart transplant centers performing fewer than nine cardiac transplants per year. Edwards et al.[5] similarly found for liver transplants that the 1-year mortality rate for centers performing fewer than 20 liver transplants per year (or lack of affiliation with a high-volume center) increased from 20 percent to 28 percent.

The criteria used by CMS to certify transplant centers for Medicare-covered whole-organ transplants require a minimum number of transplants per year for each organ type, with the exception of whole-organ pancreas transplants. Medicare coverage of pancreas transplants requires simultaneous or prior kidney transplant. CMS also considers the survival rates of transplant centers. Centers with volumes that are lower than the minimum may apply for a waiver of the condition related to volume if the facility demonstrates success with organ transplants based on survival rates.

Liver transplantation is covered for Medicare beneficiaries when performed in a pediatric hospital if the pediatric liver transplant program is operated jointly by the hospital and another facility that has been found by CMS to meet its criteria for institutional coverage. The unified program must share transplant surgeons and a quality assurance program, and the hospital must provide the specialized facilities, services, and personnel that are required by pediatric patients (children under age 18) undergoing transplantation.

**Table 21: CMS Quality Standards for Criteria for Medicare Coverage**

| Organ Type | Volume | Minimum Survival Rates | Date Effective |
|---|---|---|---|
| Kidney | 15 | n/a | 1976 |
| Heart | 12 | 1-year survival rate - 73%<br>2-year survival rate - 65% | April 6, 1987 |
| Liver | 12 | 1-year survival rate - 77 %<br>2-year survival rate - 60% | April 12, 1991 |
| Lung / Heart-Lung | 10 | 1-year survival rate - 69%<br>2-year survival rate - 62% | February 2, 1995 |
| Pancreas<br>The pancreas transplant must be performed on the same day or following a Medicare-covered kidney transplant. | | | July 1, 1999 |
| Intestine | 10 | 1-year survival rate – 65% | April 1, 2001 |

Source: Federal Register (52 FR 10935, 56 FR 15006, 60 FR 6537).

Privately paid transplants, regulated through the Organ Procurement and Transplantation Network (OPTN), do not have to meet such performance standards. Private insurance companies, however, have their own criteria, which may include volume, survival rates and transplant surgeons' certification.

UNOS does not require program volume standards; however, for a transplant center to meet UNOS membership criteria and gain certification, each transplant program must have, among other criteria, on-site qualified transplant surgeons and physicians who are credentialed in the appropriate field and who have met certain volume standards in their prior experience.

For accreditation by FAHCT, a bone marrow transplant program is required to have performed at least 10 transplants of each type (allogeneic or autologous) for which it seeks accreditation in the year prior to accreditation.

Current research suggests that hospitals providing organ transplant services should have minimum caseloads to ensure quality of care; therefore, public policy in Maryland has supported the development of a smaller number of higher volume programs over establishing new centers.

**Table 22: Summary of Minimum Facility Annual Volume Requirements**

| Transplant Program | COMAR 10.24.15 | FAHCT | CMS |
|---|---|---|---|
| Kidney | 30 | n/a | 15 |
| Pancreas | 12 | n/a | |
| Liver | 12 | n/a | 12 |
| Heart | 12 | n/a | 12 |
| Lung, Heart-Lung | 12 | n/a | 10 |
| Hematopoietic Stem Cell<br>Autologous<br>Allogeneic | <br>10<br>10 | <br>10<br>10 | <br>n/a |
| Intestines/Small Bowel | To be determined by the Commission on a case by case basis, based on the best information available at the time of application | n/a | 10 |
| Islet Cells, Hepatocytes, and Others | To be determined by the Commission on a case by case basis , based on the best information available at the time of application | n/a | n/a |

Source: COMAR 10.24.15; FAHCT, Federal Register.
n/a – not applicable.

### ♦ Option 1: Current Minimum Volume Standards

Maintain current minimum volume standards as set in the State Health Plan (Table 22). These standards are consistent with clinical research as well as standards established by CMS and FAHCT, except for kidney transplants where CMS requires 15 per year. The Technical Advisory Committee on Organ Transplant Services recommended that a minimum requirement of 25 or 30 kidney transplants annually would be acceptable.

In addition to the minimum annual volumes, the State Health Plan has also set threshold volumes (Table 23). Threshold volumes are set at a level equal to or greater than the minimum volume, as a means to prevent an adverse impact on existing programs if the Commission were to approve the development of additional transplant program capacity. As a requirement for approving an application for a new program, all existing non-federal programs must be operating at or above the threshold volumes. This is to ensure that existing programs can maintain at least the threshold volume as the new program increases its volume.

**Table 23: Threshold Volume Requirements**

| Transplant Program | COMAR 10.24.15<br>Threshold Annual Volume Requirements |
|---|---|
| Kidney | 50 |
| Pancreas | 20 |
| Liver | 20 |
| Heart | 20 |
| Lung, Heart-Lung | 20 |
| Hematopoietic Stem Cell | |
| Autologous | 10 |
| Allogeneic | 40 |

Source: COMAR 10.24.15.

The Technical Advisory Committee on Organ Transplant Services advised the Commission that neither minimum nor threshold volumes should be considered an optimal level of utilization. Instead, the standards are a method of controlling the development of an oversupply of the expensive technology and health services required for organ transplantation.

### ♦ Option 2: Revised Minimum and Threshold Volumes

Another alternative is to revise current minimum and threshold volumes to allow for more competition in the market, when appropriate.

Currently the minimum volume requirement for kidney transplant programs is double that as required by CMS for Medicare coverage. Although a trend has been shown for kidney transplants towards high volume resulting in a better outcome, it has not been significant. Six other states currently regulate kidney transplants and set minimum volume requirements. Three states are set at a minimum volume of 15 transplants per year, with the other three states at 25 transplants per year. To bring the current chapter in line with other states, the minimum volume standard for kidney transplants could be lowered to 25 transplants per year.

In addition, it may be an appropriate time to reexamine the criteria of when a new program may be approved, to include, but not limit to, the requirement that a new program can be approved only if existing programs are able to maintain at least the threshold volume, as the new program increases its volume.

### ♦ Option 3: Enforcement of Minimum Volume Standards as Condition of CON

Review current enforcement of minimum volume standards as a condition of CON for new programs, as well as enforcement of minimum volumes for existing programs. In the current State Health Plan, Policy 4 states that a CON issued by the Commission for the establishment of a new organ transplant program will require as a condition of issuance that a program achieve minimum volume standards within 36 months of beginning operation. While this policy provides oversight for new organ transplant services (CON approval provided effective after January 1999), it does not address the issue of existing programs operating below minimum utilization levels.

Proposed new programs must provide evidence of compliance of meeting the minimum volume standard within 36 months of initiation, including written comments from the OPO responsible for the regional service area in which the program will be located. As a condition of CON approval the applicant must accept a requirement that it will close, and its CON withdrawn, if:

i) it fails to meet the minimum volume for any two consecutive years, and
ii) is unable to provide an explanation acceptable to the Commission as to why it failed to maintain the minimum volume, and a clear and logical plan for how it will achieve the minimum volumes.

In addition, as in accordance to Policy 11, all transplant programs (new and existing) should report survival rate statistics and authorize release of center-specific information from the relevant certifying or accrediting body, that may be necessary for the Commission to conduct a status review of transplant programs consistent with the policies and standards in the State Health Plan.

#### ♦ Option 4: Certification and Accreditation

Another approach to enforce quality standards would be to rely on the relevant certifying and/or accrediting body where volume standards and other quality measures exist. To maintain a CON for a transplant service, the program would be required to be certified or accredited by the appropriate body, which includes the enforcement of minimum volume standards. Where program volume standards do not exist within the certification and accreditation standards, the Commission would monitor new programs.

Existing programs would be monitored by other systems currently in place, such as loss of Medicare coverage, if they do not meet CMS minimum standards.

Currently of the 12 BMT programs in the Maryland and Washington regions, 5 programs are accredited by FAHCT. Of the programs located in the State of Maryland, 2 of the 5 programs are accredited, while 2 other programs have been surveyed with accreditation pending.

The current plan states “Each Maryland transplant program should comply with all appropriate requirements of certification and/or accreditation”; the policy goes on to say that the programs must agree to seek certification and/or accreditation within the first year of operation.

## *D. Cost of Care Policies*

### 1. Cost Efficiency Standard

Organ transplant services involve complex and costly care. Policies that result in an increased number of transplant programs with each performing small numbers of transplants annually will have implications for the State’s rate-setting system and Medicare waiver as well as the quality of care.

A significant component of the CON review process involves an assessment of the financial feasibility of a project conducted with the assistance of the Health Services Cost Review Commission (HSCRC).

#### ♦ Option 1: Revenue-Neutral Agreement

By maintaining the current plan, a hospital applying to establish a new organ transplant program is required to negotiate a revenue-neutral agreement under the Guaranteed Inpatient Revenue System; however, changes will need to be made to reflect the redesign of the HSCRC rate setting system.

The redesign in rate setting methodologies means that Maryland hospitals are now monitored and held to per-case targets (charge per case targets, or CPC), which are case-mix adjusted to account for patient severity. Future year rate increases are then granted on an agreed-upon formula that includes the cost of hospital goods and services and inflation.

#### ♦ Option 2: Cost Efficiency Preference Standard

It may be appropriate to add a preference standard in the case of a comparative review of applications. In this situation, the Commission will give preference to the applicant that offers the best balance between program effectiveness and costs to the health care system as a whole. A hospital that applies for a new organ transplant program will still be required to enter into an agreement with HSCRC outlining how the transplant cases will be incorporated into the hospitals' charge per case or total patient revenue agreement with HSCRC.

## *E. Access to Care*

Policies governing access to organ transplant services in the State Health Plan focus on both geographic and financial access to care. From the standpoint of geographic access, the plan uses one-way driving time to measure access to existing organ transplant programs. Despite the clustering of transplant centers and their programs in Baltimore City and the Washington, D.C. metropolitan area, most Maryland residents are within a three hour one-way driving time to at least one of each type of transplant program. A map showing the location of transplant centers in the Maryland and Washington regions is shown in Appendix E.

Financial access to care is encouraged by requiring each hospital to develop a written policy for the provision of complete and partial charity care for indigent patients to promote access to all services regardless of an individual's ability to pay.

## *F. Other Policies*

### 1. Exemptions from Policies

The current State Health Plan allows the Commission to waive its policies of the Organ Transplant Services Chapter, for a research proposal that meets specified conditions, for a limited time.

#### ♦ Option 1: Waiver for Research Projects for Limited Time with Conditions

Maintain the current waiver for research projects. Under the current plan, research projects may be considered for an exemption from certain policies to meet the special needs and circumstances of biomedical research projects which are designed to meet a national need, and for which local

conditions offer special advantages. In order to be eligible for this exemption, the plan outlines several conditions:

1) Prior to initiation of the project the research proposal must be reviewed by each participating facility's Institutional Review Board (IRB), or equivalent institutional body; or if the institution does not have an IRB, the proposal shall have written documentation from that institution on its institutional readiness to support the patient care protocol.
2) The research proposal must receive a majority of its funding from a federal agency, other public agency, or private non-profit foundation that has authority over research on human subjects.
3) The funding agency or foundation has no financial affiliation with entities that stand to gain economically from the conduct or outcome of the trial.

#### ♦ Option 2: Requirement for All Participating Institutions to have Institutional Review Board or Equivalent

It may not be sufficient for an institution without an IRB to simply provide written documentation from that institution on its institutional readiness to support the patient care protocol, in order to achieve a waiver. An external review of the protocol should be completed before a waiver is provided.

### 2. Preference Standards in Comparative Reviews

The preference standards provide a tool for encouraging prospective applicants to address important health policy issues.

#### ♦ Option 1: Inclusion of Preference Standards

Maintain preference standards as a process in comparative CON reviews. Currently, the State Health Plan outlines one preference standard. The standard gives preference to applicants with an established prevention or early intervention program addressing the specific medical conditions leading ultimately to transplantation, with particular outreach to minority and indigent patients in the hospital's regional service area.

From a planning perspective, the use of preference standards in a highly competitive, comparative CON review can provide an incentive for hospitals to address important public policy issues. There may also be other types of preference standards that should be included in the updated State Health Plan, such as for cost efficiency.

#### ♦ Option 2: Elimination of Preference Standards

An alternative policy approach would be to eliminate preference standards from the CON review. This option would be based on the view that the general CON review criteria and standards are sufficient to evaluate applicants and that preference standards may receive greater weight than appropriate and not necessarily contribute to the selection of the best overall applicant for a new transplant program.

## 3. Merged Hospital Systems

Incentives to encourage the merger and consolidation of acute care hospitals in Maryland originated from the 1985 Health Care Cost Containment Act – Hospital Mergers and Consolidations.

State health policy favors hospital mergers by providing incentives that exempt certain types of otherwise reviewable projects from the requirement to obtain a CON. The exemption from a full CON review allows merged and consolidated hospitals access to a more limited and expedited review process for changes in hospital beds or services, and major capital expenditures. Hospital consolidation and merger projects exempt from CON review must still meet three review criteria: (1) not inconsistent with the State Health Plan, (2) will result in more efficient and effective delivery of health care services, and (3) in the public interest.

### ♦ Option 1: CON Required to Relocate Any Part of an Existing Organ Transplant Program to Another Hospital Within its Merged Hospital System

Maintain the current stance that a merged hospital system may not relocate any part of an existing organ transplant program to another hospital within its merged system.

The regionalization of organ transplant services plays an important role in the strategic planning and placement of these programs to achieve optimal balance between promoting patient access and maintaining quality of care. By regulating the entry of all new programs through CON, regionalization acts to contain unneeded programs and, accordingly, avoids the associated unnecessary health care costs.

### ♦ Option 2: Relocation without CON

Another alternative would be to increase flexibility and allow merged hospital systems to reconfigure transplant services without the requirement for a full CON review. However, this may potentially result in the relocation and/or dividing of organ transplant programs, resulting in proliferation in the absence of need and undermine the principles of regional planning for highly specialized services.

# IV. Summary

During 2001, the Commission will update the Organ Transplant Services chapter of the State Health Plan. This options paper, *Organ Transplant Services: Regulatory Issues and Policy Options,* has been prepared to assist the Commission in the plan update process. The paper identifies and examines the potential impact of a range of different policy assumptions. Table 24 summarizes the policy issues discussed in this paper and alternative approaches that could be used in updating the plan. It is the expectation of the Commission that the public comment process involved in updating the plan will identify additional policy options and approaches that will merit consideration.

**Table 24: State Health Plan for Organ Transplant Services – Summary of Alternative Policy Options**

| Policies | Option 1: Current SHP | Option 2 | Option 3 | Option 4 |
|---|---|---|---|---|
| **A Categories of Covered Transplant Programs, page 18-18** | | | | |
| | Current categories of transplant programs | Additional categories of transplant programs | | |
| **B Need Projection Policies, page 19-28** | | | | |
| 1 Definition of Planning Regions, page 19 | Consistent with OPO regional service areas | Regional service areas excluding out-of-state areas | | |
| 2 Patient Migration Patterns, page 21 | Constant patient migration patterns between base and target years | Changing migration patterns between base and target years | | |
| 3 Use Rate Assumptions in Projecting Future Cases, page 23 | Standard increase across transplant types for all age groups | Most recent 3 years of data to calculate average change for each transplant program | Constant base rate (2000) | Provide need projections for two age groups |
| 4 Length of Planning Horizon, page 29 | Three-year planning horizon | Five-year planning horizon | | |
| 5 Determination of the Need for a New Program, page 29 | Current Methodology | Revised Methodology | | |
| **C Quality of Care Policies, page 30-32** | | | | |
| 1 Minimum and Threshold Volume Standards, page 30 | Current minimum volume standards | Revised minimum and threshold volumes | Enforcement of minimum volume standards as a condition of CON | Certification and accreditation standards |
| **D Cost of Care Policies, page 34** | | | | |
| 1 Cost Efficiency Standard, page 34 | Revenue-neutral agreement | Cost efficiency preference standard | | |
| **E Access to Care, page 35** | | | | |
| **F Other Policies, page 35-36** | | | | |
| 1 Exemptions from Policies, page 35 | Waiver for research projects for a limited time with conditions | Requirement for all participating institutions to have an IRB or equivalent | | |

| Policies | Option 1: Current SHP | Option 2 | Option 3 | Option 4 |
|---|---|---|---|---|
| 2 Preference Standards in Comparative Reviews, page 36 | Inclusion of preference standards | Elimination of preference standards | | |
| 3 Merged Hospital Systems, page 37 | CON required to relocate any part of an existing organ transplant program to another hospital within its merged hospital system | Relocation without CON | | |

# V. Appendices

# Appendix A:

# Inventory of Transplant Centers by Transplant Program and Region: Maryland and Washington Regions

## Table A1: Inventory of UNOS Membership Transplant Centers by Transplant Program and Region: Maryland and Washington Regions

| Transplant Program | Region | Transplant Center |
|---|---|---|
| **Kidney** | Maryland Region | Johns Hopkins Hospital |
| | | University of Maryland Medical Center |
| | Washington Region | National Institutes of Health (MD)* |
| | | Childrens Natl Medical Ctr (DC) |
| | | Georgetown Univ Med Ctr (DC) |
| | | Howard Univ Hosp (DC) |
| | | Walter Reed Army Med Ctr (DC)* |
| | | Washington Hospital Center (DC) |
| | | Inova Fairfax Hosp (VA) |
| **Pancreas** | Maryland Region | Johns Hopkins Hospital |
| | | University of Maryland Medical Center |
| | Washington Region | National Institutes of Health (MD)* |
| | | Georgetown Univ Med Ctr (DC) |
| | | Howard Univ Hosp (DC) |
| | | Walter Reed Army Med Ctr (DC)* |
| | | Washington Hospital Center (DC) |
| | | Inova Fairfax Hosp (VA) |
| **Liver** | Maryland Region | Johns Hopkins Hospital |
| | | University of Maryland Medical Center |
| | Washington Region | Georgetown Univ Med Ctr (DC) |
| | | Howard Univ Hosp (DC) |
| | | Inova Fairfax Hosp (VA) |
| **Heart** | Maryland Region | Johns Hopkins Hospital |
| | | University of Maryland Medical Center |
| | Washington Region | Childrens Natl Medical Ctr (DC) |
| | | Washington Hospital Center (DC) |
| | | Inova Fairfax Hosp (VA) |
| **Heart-Lung / Lung** | Maryland Region | Johns Hopkins Hospital |
| | | University of Maryland Medical Center |
| | Washington Region | Inova Fairfax Hosp (VA) |
| **Intestine, Small Bowel** | Maryland Region | Johns Hopkins Hospital |
| | Washington Region | None |
| **Islets, Hepatocytes** | Maryland Region | University of Maryland Hospital |
| | Washington Region | National Institutes of Health (MD)* |
| | | Walter Reed Army Med Ctr (DC)* |

Source: UNOS. http://www.unos.org/frame_Default.asp?Category=Resources. Accessed August 13, 2001.
* federal hospital – not included in regional planning.

## Table A2: Inventory of Bone Marrow Transplant Centers by Region: Maryland and Washington Regions

| Transplant Program | Region | Transplant Center |
|---|---|---|
| **Hematopoietic Stem Cell** | Maryland Region | Greater Baltimore Medical Center |
| | | Johns Hopkins Hospital |
| | | Sinai Hospital |
| | | University of Maryland Medical Center |
| | Washington Region | Holy Cross Hospital (MD) |
| | | National Institutes of Health (MD)* |
| | | Childrens Natl Medical Ctr (DC) |
| | | Georgetown Univ Med Ctr (DC) |
| | | George Washington (DC) |
| | | Walter Reed Army Med Ctr (DC)* |
| | | Washington Hospital Center (DC) |
| | | Inova Fairfax Hosp (VA) |

Source: COMAR 10.24.15
*federal hospital – not included in regional planning.

# Appendix B:
# Utilization Trends

**Table B1. Utilization of Regional Kidney Transplant Programs: 1990 - 1999**

| Regional Service Area | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 |
|---|---|---|---|---|---|---|---|---|---|---|
| **Maryland Region** | | | | | | | | | | |
| Johns Hopkins Bayview | 19 | 24 | 33 | 35 | 31 | 32 | 32 | 1 | 0 | 0 |
| Johns Hopkins Hospital | 60 | 45 | 40 | 53 | 59 | 66 | 70 | 113 | 118 | 164 |
| Univ of Maryland | 12 | 42 | 76 | 106 | 114 | 141 | 165 | 197 | 257 | 329 |
| **Subtotal:** | **91** | **111** | **149** | **194** | **204** | **239** | **267** | **311** | **375** | **493** |
| **Washington Region** | | | | | | | | | | |
| Shady Grove Adventist | - | - | 0 | 0 | 2 | 2 | 5 | 3 | 4 | - |
| Childrens Natl Medical Ctr | 6 | 11 | 9 | 12 | 4 | 2 | 3 | 2 | 11 | 5 |
| George Washington Univ | 6 | 13 | 4 | 3 | 7 | 1 | 1 | - | - | - |
| Georgetown Univ Med Ctr | 20 | 32 | 26 | 22 | 33 | 29 | 29 | 18 | 48 | 66 |
| Howard Univ Hosp | 11 | 15 | 14 | 14 | 10 | 7 | 7 | 5 | 7 | 10 |
| Walter Reed Army Med* | 22 | 21 | 25 | 21 | 11 | 23 | 25 | 27 | 44 | 34 |
| Washington Hospital | 109 | 121 | 131 | 87 | 99 | 102 | 94 | 82 | 95 | 110 |
| Inova Fairfax Hosp | - | - | 7 | 19 | 31 | 32 | 44 | 49 | 53 | 79 |
| **Subtotal:** | **174** | **213** | **216** | **178** | **197** | **198** | **208** | **181** | **247** | **299** |
| **Total** | **265** | **324** | **365** | **372** | **401** | **437** | **475** | **492** | **622** | **792** |

Source: 2000 OPTN/SR AR 1990-1999. HHS/HRSA/OSP/DOT; UNOS.[b]
UNOS Scientific Registry Data as of September 5, 2000.
Note: - Denotes center not yet operating or program withdrawn.
* federal hospital – not included in regional planning.

**Table B2. Utilization of Regional Pancreas Transplant Programs: 1990 - 1999**

| Regional Service Area | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 |
|---|---|---|---|---|---|---|---|---|---|---|
| **Maryland Region** | | | | | | | | | | |
| Johns Hopkins Hospital | 0 | 0 | 1 | 1 | 2 | 1 | 3 | 8 | 2 | 11 |
| Univ of Maryland | - | 0 | 5 | 8 | 16 | 15 | 43 | 43 | 39 | 69 |
| **Subtotal:** | **0** | **0** | **6** | **9** | **18** | **16** | **46** | **51** | **41** | **80** |
| **Washington Region** | | | | | | | | | | |
| Georgetown Univ Med Ctr | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Walter Reed Army Med* | - | 0 | 0 | 0 | 0 | 0 | 1 | 1 | 3 | 1 |
| Washington Hospital Ctr | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 1 | 4 | 1 |
| Inova Fairfax Hosp | - | - | 0 | 0 | 0 | 0 | 1 | 1 | 0 | 1 |
| **Subtotal:** | **0** | **0** | **0** | **0** | **0** | **0** | **4** | **3** | **7** | **4** |
| **Total** | **0** | **0** | **6** | **9** | **18** | **16** | **50** | **54** | **48** | **84** |

Source: 2000 OPTN/SR AR 1990-1999. HHS/HRSA/OSP/DOT; UNOS.[b]
UNOS Scientific Registry Data as of September 5, 2000.
Note: - Denotes center not yet operating or program withdrawn.
* federal hospital – not included in regional planning.

**Table B3. Utilization of Regional Kidney-Pancreas Transplant Programs: 1990 - 1999**

| Regional Service Area | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 |
|---|---|---|---|---|---|---|---|---|---|---|
| **Maryland Region** | | | | | | | | | | |
| Johns Hopkins Hospital | 0 | 0 | 1 | 2 | 4 | 8 | 16 | 5 | 10 | 7 |
| Univ of Maryland | - | 9 | 19 | 23 | 18 | 47 | 29 | 23 | 24 | 14 |
| **Subtotal:** | **0** | **9** | **20** | **25** | **22** | **55** | **45** | **28** | **34** | **21** |
| **Washington Region** | | | | | | | | | | |
| George Washington Univ | 2 | 0 | 0 | 0 | 1 | 0 | 0 | - | - | - |
| Georgetown Univ Med Ctr | 6 | 3 | 4 | 7 | 3 | 7 | 2 | 3 | 2 | 0 |
| Walter Reed Army Med* | - | 0 | 1 | 2 | 3 | 1 | 3 | 1 | 4 | 2 |
| Washington Hospital Ctr | 14 | 14 | 21 | 14 | 16 | 13 | 13 | 13 | 14 | 3 |
| Inova Fairfax Hosp | - | - | 2 | 3 | 7 | 3 | 5 | 4 | 7 | 8 |
| **Subtotal:** | **22** | **17** | **28** | **26** | **30** | **24** | **23** | **21** | **27** | **13** |
| **Total** | **22** | **26** | **48** | **51** | **52** | **79** | **68** | **49** | **61** | **34** |

Source: 2000 OPTN/SR AR 1990-1999. HHS/HRSA/OSP/DOT; UNOS.[6]
UNOS Scientific Registry Data as of September 5, 2000.
Note: - Denotes center not yet operating or program withdrawn.
* federal hospital – not included in regional planning.

**Table B4. Utilization of Regional Liver Transplant Programs: 1990 - 1999**

| Regional Service Area | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 |
|---|---|---|---|---|---|---|---|---|---|---|
| **Maryland Region** | | | | | | | | | | |
| Johns Hopkins Hospital | 37 | 43 | 54 | 54 | 61 | 50 | 45 | 46 | 65 | 53 |
| Univ of Maryland | - | - | - | - | 1 | 17 | 29 | 24 | 15 | 23 |
| **Subtotal:** | **37** | **43** | **54** | **54** | **62** | **67** | **74** | **70** | **80** | **76** |
| **Washington Region** | | | | | | | | | | |
| Howard Univ Hosp | 0 | 1 | 7 | 5 | 14 | 5 | 6 | 5 | 0 | 1 |
| Inova Fairfax Hosp | - | - | 4 | 14 | 18 | 36 | 53 | 36 | 30 | 25 |
| Georgetown Univ Med Ctr | - | - | - | - | - | - | - | - | 14 | 31 |
| **Subtotal:** | **0** | **1** | **11** | **19** | **32** | **41** | **59** | **41** | **44** | **57** |
| **Total** | **37** | **44** | **65** | **73** | **94** | **108** | **133** | **111** | **124** | **133** |

Source: 2000 OPTN/SR AR 1990-1999. HHS/HRSA/OSP/DOT; UNOS.[6]
UNOS Scientific Registry Data as of September 5, 2000.
Note: - Denotes center not yet operating or program withdrawn.

**Table B5. Utilization of Regional Heart Transplant Programs: 1990 - 1999**

| Regional Service Area | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 |
|---|---|---|---|---|---|---|---|---|---|---|
| **Maryland Region** | | | | | | | | | | |
| Johns Hopkins Hospital | 16 | 18 | 16 | 19 | 14 | 24 | 23 | 15 | 19 | 23 |
| Univ of Maryland | 2 | 3 | 6 | 6 | 3 | 12 | 9 | 6 | 6 | 4 |
| **Subtotal:** | **18** | **21** | **22** | **25** | **17** | **36** | **32** | **21** | **25** | **27** |
| **Washington Region** | | | | | | | | | | |
| Childrens Natl Medical Ctr | 2 | 3 | 1 | 4 | 3 | 2 | 1 | 3 | 3 | 2 |
| George Washington Univ | 4 | 4 | 1 | 2 | 0 | 1 | - | - | - | - |
| Georgetown Univ Med Ctr | 2 | 5 | 1 | 4 | 2 | 2 | 0 | - | - | - |
| Washington Hospital Ctr | 10 | 13 | 10 | 13 | 9 | 13 | 16 | 13 | 9 | 8 |
| Inova Fairfax Hosp | 12 | 10 | 12 | 19 | 22 | 12 | 16 | 7 | 15 | 13 |
| **Subtotal:** | **30** | **35** | **25** | **42** | **36** | **30** | **33** | **23** | **27** | **23** |
| **Total** | **48** | **56** | **47** | **67** | **53** | **66** | **65** | **44** | **52** | **50** |

Source: 2000 OPTN/SR AR 1990-1999. HHS/HRSA/OSP/DOT; UNOS.[6]
UNOS Scientific Registry Data as of September 5, 2000.
Note: - Denotes center not yet operating or program withdrawn.

**Table B6. Utilization of Regional Lung Transplant Programs: 1990 - 1999**

| Regional Service Area | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 |
|---|---|---|---|---|---|---|---|---|---|---|
| **Maryland Region** | | | | | | | | | | |
| Johns Hopkins Hospital | - | - | - | 1 | 3 | 7 | 9 | 6 | 16 | 29 |
| Univ of Maryland | - | - | 2 | 3 | 2 | 10 | 20 | 8 | 11 | 4 |
| **Subtotal:** | **0** | **0** | **2** | **4** | **5** | **17** | **29** | **14** | **27** | **33** |
| **Washington Region** | | | | | | | | | | |
| Inova Fairfax Hosp | - | 1 | 1 | 2 | 6 | 2 | 4 | 3 | 10 | 13 |
| **Subtotal:** | **0** | **1** | **1** | **2** | **6** | **2** | **4** | **3** | **10** | **13** |
| **Total** | **0** | **1** | **1** | **6** | **11** | **19** | **33** | **17** | **37** | **46** |

Source: 2000 OPTN/SR AR 1990-1999. HHS/HRSA/OSP/DOT; UNOS.[6]
UNOS Scientific Registry Data as of September 5, 2000.
Note: - Denotes center not yet operating or program withdrawn.

## Table B7. Utilization of Regional Heart-Lung Transplant Programs: 1990 - 1999

| Regional Service Area | 1990 | 1991 | 1992 | 1993 | 1994 | 1995 | 1996 | 1997 | 1998 | 1999 |
|---|---|---|---|---|---|---|---|---|---|---|
| **Maryland Region** | | | | | | | | | | |
| Johns Hopkins Hospital | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Univ of Maryland | - | - | - | - | - | - | 1 | - | 0 | 0 |
| **Subtotal:** | **3** | **0** | **0** | **0** | **0** | **0** | **1** | **0** | **0** | **1** |
| **Washington Region** | | | | | | | | | | |
| Inova Fairfax Hosp | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| **Subtotal:** | **0** | **0** | **0** | **0** | **0** | **0** | **0** | **1** | **0** | **0** |
| **Total** | **3** | **0** | **0** | **0** | **0** | **0** | **1** | **1** | **0** | **1** |

Source: 2000 OPTN/SR AR 1990-1999. HHS/HRSA/OSP/DOT; UNOS.[6]
UNOS Scientific Registry Data as of September 5, 2000.
Note: - Denotes center not yet operating or program withdrawn.

## Table B8. Utilization of Regional Autologous Hematopoietic Stem Cell Transplant Programs: 1997 - 1999

| Regional Service Area | 1997 | 1998 | 1999 |
|---|---|---|---|
| **Maryland Region** | | | |
| Greater Baltimore Med. Ctr | 13 | 16 | 9 |
| Johns Hopkins Hospital | 151 | 123 | 90 |
| Sinai Hospital | - | 1 | 5 |
| Univ of Maryland | 54 | 101 | 121 |
| **Subtotal:** | **218** | **241** | **225** |
| **Washington Region** | | | |
| Childrens Natl Medical Ctr | 2 | 5 | 7 |
| Holy Cross Hospital | 6 | 9 | 5 |
| Inova Fairfax Hosp | 46 | 67 | 56 |
| Washington Hospital Ctr | 4 | 4 | 4 |
| Georgetown Univ Med Ctr | 55 | 73 | 30 |
| George Washington | 21 | 8 | 12 |
| **Subtotal:** | **134** | **166** | **114** |
| **Total** | **352** | **407** | **339** |

Sources: 1997-1999 data –MD Discharge Abstract, DC Discharge Data, Fairfax Hospital.
Note: Fairfax Hospital 1997 data does not separate out autologous and allogeneic transplants. Tables B8 and B9 assume a 75%/25% split (autologous/allogeneic).
Autologous utilization is based on cases not total infusions per case.

## Table B9. Utilization of Regional Allogeneic Hematopoietic Stem Cell Transplant Programs: 1997 - 1999

| Regional Service Area | 1997 | 1998 | 1999 |
|---|---|---|---|
| **Maryland Region** | | | |
| Johns Hopkins Hospital | 78 | 84 | 87 |
| Univ of Maryland | 3 | 19 | 26 |
| **Subtotal:** | **81** | **103** | **113** |
| **Washington Region** | | | |
| Childrens Natl Medical Ctr | 6 | 7 | 13 |
| Inova Fairfax Hosp | 15 | 5 | 2 |
| Georgetown Univ Med Ctr | 10 | 13 | 4 |
| George Washington | 2 | 2 | 3 |
| **Subtotal:** | **33** | **27** | **22** |
| **Total** | **114** | **130** | **135** |

Sources: 1997-1999 data –MD Discharge Abstract, DC Discharge Data, Fairfax Hospital.
Note: Fairfax Hospital 1997 data does not separate out autologous and allogeneic transplants. Tables B8 and B9 assume a 75%/25% split (autologous/allogeneic).

# Appendix C:

# Comparison of Alternate Use Rate Assumptions on Projected Organ Transplant Need

**Table C1: Comparison of Alternate Use Rate Assumptions on Projected Kidney Transplant Cases for 2003 by Projection Method and Region: Maryland and Washington Regions**

| Projection Method | Patient Jurisdiction | All Ages | | Pediatrics (less than 18) | | Adults (18 and older) | |
|---|---|---|---|---|---|---|---|
| | | *Use Rate* | *Cases* | *Use Rate* | *Cases* | *Use Rate* | *Cases* |
| Same as Current SHP | | | | | | | |
| | MD Region | 14.01 | 479 | | | | |
| | DC Region | 7.26 | 306 | | | | |
| % Change in use rate | | | | | | | |
| | MD Region | 20.23 | 691 | 0.48 | 4 | 28.42 | 725 |
| | DC Region | 6.46 | 272 | 0.43 | 5 | 8.71 | 278 |
| Constant Rate | | | | | | | |
| | MD Region | 10.01 | 342 | 1.23 | 11 | 13.01 | 332 |
| | DC Region | 6.05 | 255 | 1.15 | 12 | 7.67 | 245 |

Sources: UNOS, data as of July 13, 2001. Population data: MD – Data June 1999 Md Dept. of Planning, with Feb. 2000 update; DC – US Census; VA – Virginia Employment Commission, August 24, 1999.

**Table C2: Comparison of Alternate Use Rate Assumptions on Projected Pancreas Transplant Cases for 2003 by Projection Method and Region: Maryland and Washington Regions**

| Projection Method | Patient Jurisdiction | All Ages | | Pediatrics (less than 18) | | Adults (18 and older) | |
|---|---|---|---|---|---|---|---|
| | | *Use Rate* | *Cases* | *Use Rate* | *Cases* | *Use Rate* | *Cases* |
| Same as Current SHP | | | | | | | |
| | MD Region | 1.45 | 49 | | | | |
| | DC Region | 0.69 | 29 | | | | |
| % Change in use rate | | | | | | | |
| | MD Region | 1.32 | 45 | 0.00 | 0 | 1.80 | 46 |
| | DC Region | 0.31 | 13 | 0.01 | 0 | 0.46 | 15 |
| Constant Rate | | | | | | | |
| | MD Region | 1.03 | 35 | 0.00 | 0 | 1.41 | 36 |
| | DC Region | 0.57 | 24 | 0.10 | 1 | 0.73 | 23 |

Sources: UNOS, data as of July 13, 2001. Population data: MD – Data June 1999 Md Dept. of Planning, with Feb. 2000 update; DC – US Census; VA – Virginia Employment Commission, August 24, 1999.

**Table C3: Comparison of Alternate Use Rate Assumptions on Projected Liver Transplant Cases for 2003 by Projection Method and Region: Maryland and Washington Regions**

| Projection Method | Patient Jurisdiction | All Ages | | Pediatrics (less than 18) | | Adults (18 and older) | |
|---|---|---|---|---|---|---|---|
| | | *Use Rate* | *Cases* | *Use Rate* | *Cases* | *Use Rate* | *Cases* |
| Same as Current SHP | | | | | | | |
| | MD Region | 2.58 | 88 | | | | |
| | DC Region | 1.95 | 82 | | | | |
| % Change in use rate | | | | | | | |
| | MD Region | 1.90 | 65 | 0.95 | 8 | 2.15 | 55 |
| | DC Region | 1.66 | 70 | 0.82 | 9 | 1.89 | 60 |
| Constant Rate | | | | | | | |
| | MD Region | 1.84 | 63 | 0.29 | 3 | 2.83 | 72 |
| | DC Region | 1.63 | 69 | 0.26 | 3 | 2.44 | 78 |

Sources: UNOS, data as of July 13, 2001. Population data: MD – Data June 1999 Md Dept. of Planning, with Feb. 2000 update; DC – US Census; VA – Virginia Employment Commission, August 24, 1999.

**Table C4: Comparison of Alternate Use Rate Assumptions on Projected Heart Transplant Cases for 2003 by Projection Method and Region: Maryland and Washington Regions**

| Projection Method | Patient Jurisdiction | All Ages | | Pediatrics (less than 18) | | Adults (18 and older) | |
|---|---|---|---|---|---|---|---|
| | | *Use Rate* | *Cases* | *Use Rate* | *Cases* | *Use Rate* | *Cases* |
| Same as Current SHP | | | | | | | |
| | MD Region | 0.93 | 32 | | | | |
| | DC Region | 0.62 | 26 | | | | |
| % Change in use rate | | | | | | | |
| | MD Region | 0.39 | 13 | 0.08 | 1 | 0.44 | 11 |
| | DC Region | 0.60 | 25 | 0.16 | 2 | 0.64 | 20 |
| Constant Rate | | | | | | | |
| | MD Region | 0.66 | 23 | 0.08 | 1 | 0.86 | 22 |
| | DC Region | 0.51 | 22 | 0.16 | 2 | 0.63 | 20 |

Sources: UNOS, data as of July 13, 2001. Population data: MD – Data June 1999 Md Dept. of Planning, with Feb. 2000 update; DC – US Census; VA – Virginia Employment Commission, August 24, 1999.

**Table C5: Comparison of Alternate Use Rate Assumptions on Projected Lung Transplant Cases for 2003 by Projection Method and Region: Maryland and Washington Regions**

| Projection Method | Patient Jurisdiction | All Ages | | Pediatrics (less than 18) | | Adults (18 and older) | |
|---|---|---|---|---|---|---|---|
| | | *Use Rate* | *Cases* | *Use Rate* | *Cases* | *Use Rate* | *Cases* |
| Same as Current SHP | | | | | | | |
| | MD Region | 0.65 | 22 | | | | |
| | DC Region | 0.51 | 22 | | | | |
| % Change in use rate | | | | | | | |
| | MD Region | 0.37 | 13 | 0.02 | 0 | 0.56 | 14 |
| | DC Region | 1.12 | 47 | 0.07 | 1 | 1.33 | 42 |
| Constant Rate | | | | | | | |
| | MD Region | 0.46 | 16 | 0.16 | 1 | 0.56 | 14 |
| | DC Region | 0.42 | 18 | 0.07 | 1 | 0.54 | 17 |

Sources: UNOS, data as of July 13, 2001. Population data: MD – Data June 1999 Md Dept. of Planning, with Feb. 2000 update; DC – US Census; VA – Virginia Employment Commission, August 24, 1999.

**Table C6: Comparison of Alternate Use Rate Assumptions on Projected Autologous Hematopoietic Stem Cell Transplant Cases for 2003 by Projection Method and Region: Maryland and Washington Regions**

| Projection Method | Patient Jurisdiction | All Ages | | Pediatrics (less than 18) | | Adults (18 and older) | |
|---|---|---|---|---|---|---|---|
| | | *Use Rate* | *Cases* | *Use Rate* | *Cases* | *Use Rate* | *Cases* |
| Same as Current SHP | | | | | | | |
| | MD Region | 6.69 | 229 | | | | |
| | DC Region | 3.59 | 151 | | | | |
| % Change in use rate | | | | | | | |
| | MD Region | 6.31 | 216 | 1.02 | 9 | 8.17 | 208 |
| | DC Region | 2.10 | 89 | 0.29 | 3 | 2.70 | 86 |
| Constant Rate | | | | | | | |
| | MD Region | 4.78 | 163 | 0.76 | 7 | 6.18 | 158 |
| | DC Region | 2.99 | 126 | 0.47 | 5 | 3.82 | 122 |

Source: Maryland Discharge Abstract, as of July 2001; DC Discharge Data as of July 2001; HSANV; Fairfax Hospital. Population Data: MD – Data June 1999 Md Dept. of Planning, with Feb. 2000 update; DC – US Census; VA – Virginia Employment Commission, August 24, 1999.

**Table C7: Comparison of Alternate Use Rate Assumptions on Projected Allogeneic Hematopoietic Stem Cell Transplant Cases for 2003 by Projection Method and Region: Maryland and Washington Regions**

| Projection Method | Patient Jurisdiction | All Ages | | Pediatrics (less than 18) | | Adults (18 and older) | |
|---|---|---|---|---|---|---|---|
| | | *Use Rate* | *Cases* | *Use Rate* | *Cases* | *Use Rate* | *Cases* |
| Same as Current SHP | | | | | | | |
| | MD Region | 1.90 | 65 | | | | |
| | DC Region | 1.05 | 44 | | | | |
| % Change in use rate | | | | | | | |
| | MD Region | 5.63 | 192 | 4.99 | 43 | 5.84 | 149 |
| | DC Region | 0.79 | 33 | 0.76 | 8 | 0.93 | 30 |
| Constant Rate | | | | | | | |
| | MD Region | 1.36 | 46 | 1.23 | 11 | 1.40 | 36 |
| | DC Region | 0.87 | 37 | 0.80 | 8 | 0.90 | 29 |

Source: Maryland Discharge Abstract, as of July 2001; DC Discharge Data as of July 2001; HSANV; Fairfax Hospital. Population data: MD – Data June 1999 Md Dept. of Planning, with Feb. 2000 update; DC – US Census; VA – Virginia Employment Commission, August 24, 1999.

# Appendix D:
# Determination of the Need for a New Program

**Table D1: Projected Transplant Cases and Need for New Programs by Regional Service Area: Target Year 2003**

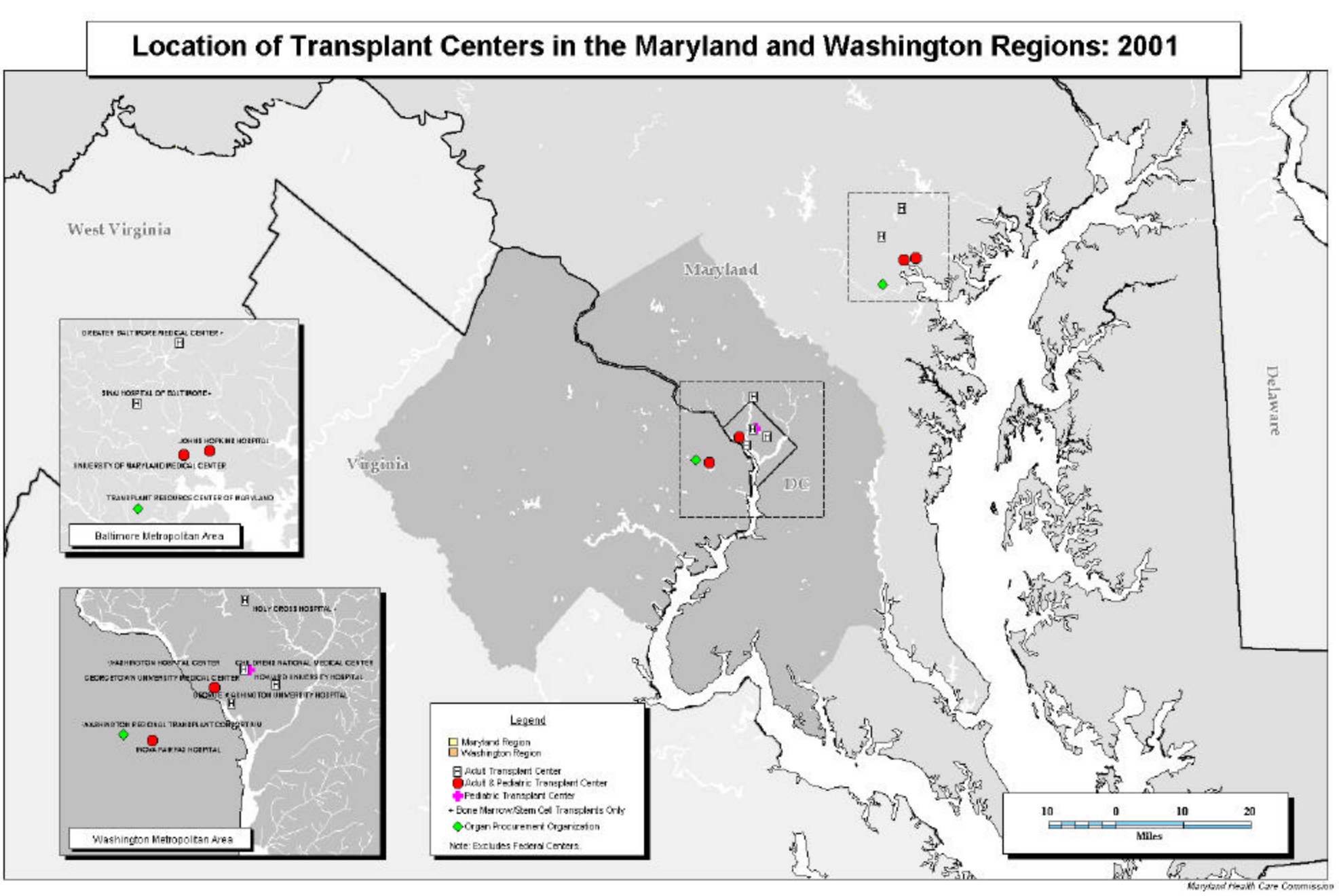
| Transplant Program by Facility Region | Number of Tx Programs | Av. Annual Tx Cases (1998-2000)* | Tx Cases (2000)† | Projected Transplant Cases (2003)‡ | Additional Cases (iii) | Minimum/ Threshold Volume Standard | Projected > Threshold Volume (i) | Minimum Volume Standard Met (1999) | Threshold Volume Standard Met (ii) | New Program Considered |
|---|---|---|---|---|---|---|---|---|---|---|
| Kidney | | | | | | | | | | |
| MD | 2 | 502 | 596 | 731 | 135 | 30/50 | Yes | 2 Yes | 2 Yes | Yes |
| Washington | 5 | 259 | 256 | 286 | 30 | | No | 2 No, 3 Yes | 2 No, 3 Yes | No |
| Pancreas | | | | | | | | | | |
| MD | 2 | 81 | 76 | 90 | 14 | 12/20 | No | 2 Yes | 1 No, 1 Yes | No |
| Washington | 3 | 19 | 15 | 16 | 1 | | No | 3 No | 3 No | No |
| Liver | | | | | | | | | | |
| MD | 2 | 79 | 80 | 82 | 2 | 12/20 | No | 2 Yes | 2 Yes | No |
| Washington | 3 | 52 | 56 | 55 | -1 | | No | 1 No, 2 Yes | 1 No, 2 Yes | No |
| Heart | | | | | | | | | | |
| MD | 2 | 24 | 21 | 20 | -1 | 12/20 | No | 1 No, 1 Yes | 1 No, 1 Yes | No |
| Washington | 3 | 22 | 16 | 23 | 7 | | No | 2 No, 1 Yes | 3 No | No |
| Lung | | | | | | | | | | |
| MD | 2 | 28 | 25 | 33 | 8 | 12/20 | No | 1 No, 1 Yes | 1 No, 1 Yes | No |
| Washington | 1 | 14 | 19 | 23 | 4 | | No | 1 Yes | 1 No | No |
| Autologous BMT | | | | | | | | | | |
| MD | 4 | 228 | 225 | 258 | 33 | 10/10 | Yes | 2 No, 2 Yes | 2 No, 2 Yes | No |
| Washington | 6 | 138 | 114 | 70 | -44 | | No | 3 No, 3 Yes | 3 No, 3 Yes | No |
| Allogeneic BMT | | | | | | | | | | |
| MD | 2 | 99 | 113 | 200 | 87 | 10/40 | Yes | 2 Yes | 1 No, 1 Yes | No |
| Washington | 4 | 27 | 22 | 31 | 9 | | No | 3 No, 1 Yes | 4 No | No |

An application for a new program will be considered only if the following criteria are met:

i. The difference between the projected transplant cases (3-year planning horizon) and the transplant cases in the current year is greater than the threshold utilization standard;
ii. All programs of a specific type within the region meet or exceed the threshold volume in the most current full year of data available;
iii. There is a positive trend in the utilization of that program type in the region as a whole, over the most recent 3 years of data available; and
iv. The introduction of a new program will not result in a center dropping below the minimum volume standards.

* Average annual transplant cases based on 1997 to 1999 data for autologous and allogeneic bone marrow transplants.
† Transplant cases based on 1999 data for autologous and allogeneic bone marrow transplants.
‡ Projected cases based on: III.B.1-Option 1; III.B.2-Option 1; III.B.3-Option 2 (all ages).

# Appendix E:
# Location of Transplant Centers in the Maryland and Washington Regions: 2001


Location of Transplant Centers in the Maryland and Washington Regions: 2001
West Virginia
Maryland
Virginia
DC
Delaware
Baltimore Metropolitan Area
Washington Metropolitan Area
Legend
Maryland Region
Washington Region
Adult Transplant Center
Adult & Pediatric Transplant Center
Pediatric Transplant Center
Bone Marrow/Stem Cell Transplants Only
Organ Procurement Organization
Note: Excludes Federal Centers.
10 0 10 20
Miles
Maryland Health Care Commission

# VI. References

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